EXHIBIT 1

TRANSCRIPT OF 2/15/2018 DEPOSITION OF MICHAEL MILLER, M.D.

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Page 1
1
          IN THE UNITED STATES DISTRICT COURT
 2
               FOR THE DISTRICT OF NEVADA
3
4
 5
    AMARIN PHARMA, INC., : Case No.:
6
    et al.,
                              : 2:16-CV-02525-MMD-NJK
7
               Plaintiffs :
                              : (Consolidated with
8
    vs.
9
    WEST-WARD PHARMACEUTICALS: 2:16-CV-02562-MMD-NJK,
10
    CORP., et al., : 2:16-CV-02658-MMD-MJK,
               Defendants. : 2:17-CV-02641-RFB-GWF)
11
12
13
14
15
      Videotaped Deposition of MICHAEL MILLER, M.D.
16
17
                    Washington, D.C.
               Thursday, February 15, 2018
18
19
                        8:03 a.m.
20
21
22
    Job No. 225981
    Pages: 1 - 272
23
24
    Reported by: Dana C. Ryan, RPR, CRR
25
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1	Pag	ge 2	1	A P P E A R A N C E S C O N T I N U E D	Page 4
2			2		
3			3	ON BEHALF OF THE DEFENDANTS	
4			4	DR. REDDY'S LABORATORIES, INC. AND	
5	February 15, 2018		5	DR. REDDY'S LABORATORIES LIMITED:	
6	8:03 a.m.		6	CAROLINE SUN, ESQ.	
7			7	Budd Larner, P.C.	
8			8	150 John F. Kennedy Parkway	
9			9	Short Hills, New Jersey 07078	
10	Videotaped Deposition of MICHAEL MILLER,		10		
11	M.D., held at the law offices of Covington &		11		
12	Burling LLP, One City Center, 850 Tenth Street,		12		
13	Northwest, Washington, D.C., pursuant to the		13	ON BEHALF OF THE DEFENDANT	
14	Federal Rules of Civil Procedure, before Dana C.		14	TEVA PHARMACEUTICALS USA INC.:	
15	Ryan, Registered Professional Reporter, Certified		15	CHANDRIKA VIRA, ESQ.	
16	Realtime Reporter and Notary Public in and for the		16	Sterne, Kessler, Goldstein &	
17	District of Columbia.		17	Fox, P.L.L.C.	
18			18	1100 New York Avenue, Northwest	
19			19	Washington, D.C. 20005	
20			20		
21			21		
22			22		
23			23		
24			24		
25			25		
	Pac	ge 3			Dago E
1	APPEARANCES	.gc J	1	A P P E A R A N C E S C O N T I N U E D	Page 5
2	APPEARANCES	ge 3	1	APPEARANCES CONTINUED	rage 5
	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF:	96 3		APPEARANCES CONTINUED Also present:	rage 5
2	APPEARANCES	96 3	2		rage s
2	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF:	ge 3	2	Also present:	rage 5
2 3 4	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ.	90 3	2 3 4	Also present: Francis Solomon, Videographer	rage 5
2 3 4 5	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ.	90 3	2 3 4 5	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP	ge 3	2 3 4 5	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center	ge	2 3 4 5 6	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest	ge 3	2 3 4 5 6 7 8	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest	ge J	2 3 4 5 6 7 8	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
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2 3 4 5 6 7 8 9 10	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest	ge J	2 3 4 5 6 7 8 9 10	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
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2 3 4 5 6 7 8 9 10 11 12 13	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001		2 3 4 5 6 7 8 9 10 11 12	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS		2 3 4 5 6 7 8 9 10 11 12 13	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14	A P P E A R A N C E S ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD		2 3 4 5 6 7 8 9 10 11 12 13 14 15	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED:		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ.		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP Brookfield Place		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP Brookfield Place 200 Vesey Street, 20th Floor		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP Brookfield Place 200 Vesey Street, 20th Floor		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP Brookfield Place 200 Vesey Street, 20th Floor		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	ON BEHALF OF THE PLAINTIFF: MICHAEL N. KENNEDY, ESQ. HAN PARK, ESQ. Covington & Burling LLP One City Center 850 Tenth Street, Northwest Washington, D.C. 20001 ON BEHALF OF THE DEFENDANTS WEST-WARD PHARMACEUTICALS CORP. AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED: ALAN B. CLEMENT, ESQ. Locke Lord LLP Brookfield Place 200 Vesey Street, 20th Floor		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Also present: Francis Solomon, Videographer Jennifer Scarpati	rage 5

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4					4	Exhibit 13	-	75	
5					5		Bates Stamped AMRN02702696		
6					6	Exhibit 14	U.S. Patent Number 8,293,728	88	
7		EXHIBITS			7	Exhibit 15	_	122	
8		(Attached to the Transcript)			8		Of The National Cholesterol		
9	MILLER DEPO		PAGE:		9		Education Program Expert		
10		Notice Of Deposition	16		10		Panel On Detection,		
11	Exhibit 2	Declaration Of Michael	22		11		Evaluation, And Treatment Of		
12		Miller, M.D., On			12		High Blood Cholesterol In		
13		Claim Construction			13		Adults (Adult Treatment Panel		
14	Exhibit 3	Materials Considered	24		14		III) Final Report, Bates		
15	Exhibit 4	Reply Declaration Of Michael	27		15		Stamped AMRN00289915 Through		
16		Miller, M.D., On Claim			16		00290194		
17		Construction			17	Exhibit 16	Declaration Of Harold E. Bays	136	
18	Exhibit 5	Curriculum Vitae	39		18		Bates Stamped AMRN03058234		
19	Exhibit 6	March 4, 2010 Email Chain	44		19		Through 03059940		
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23		Meeting With Dr. Miller Bates			23		Through 00008969		
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2	((Attached to the Transcript)			2	(1	Attached to the Transcript)		
3	MILLER DEPO	OSITION	PAGE:		3	MILLER DEPOS	SITION	PAGE:	
4	Exhibit 8	Dr. Miller's Consulting Time	60		4	Exhibit 18	Document Titled	177	
5		For Amarin For September			5		Hypertriglyceridemia And		
6		Through December 2010, Bates			6		Cardiovascular Risk		
7		Stamped AMRN02739796			7		Reduction Bates Stamped		
8	Exhibit 9	Dr. Miller's Consulting Time	62		8		ICOSAPENT_DFNDTS00010211		
9		For Amarin For January			9		Through 00010225		
10		Through June 2011, Bates			10	Exhibit 19	Document Titled Triglycerides	187	
11		Stamped AMRN02769565			11		And Cardiovascular Disease, A		
12	Exhibit 10	Slide Deck Titled 2014	63		12		Scientific Statement From The		
13		Clinical Development			13		American Heart Association		
14		Department Goals - Status,			14	Exhibit 20	Document Titled Efficacy And	257	
15		Bates Stamped AMRN03121925			15		Safety Of Cholesterol-		
16		Through 03121931			16		Lowering Treatment:		
17	Exhibit 11	Dr. Miller's Consulting Time	64		17		Prospective Meta-Analysis Of		
18		For Amarin For July Through			18		Data From 90056 Participants		
19		December 2011, Bates Stamped			19		In 14 Randomised Trials Of		
20		AMRN01077327			20		Statins, Bates Stamped		
21	Exhibit 12	November 19, 2012 Email Chain	67		21		AMRN03130228 Through 03130239		
22		With Attachment, Bates			22				
23		Stamped AMRN01638777 Through			23				
24		01638778			24				
25					25				
					1				

0	PVALITIVA	ITON DI COONSEL FOR THE DEFENDANTS				
9	WEST-WARD PHARMACEUTICALS CORP. AND					
10	WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED					
11	BY MR	. CLEMENT:				
12	Q	Good morning, Dr. Miller.				
13	А	Good morning.				
14	Q	My name is Alan Clement. I represent				
15	West-Ward	Pharmaceuticals in this case, and we're				
16	going to ha	ave your deposition today.				
17		Have you ever been deposed before?				
18	А	I have.				
19	Q	Okay. And in what type of case was				
20	that or	how many let me ask this. How many				
21	times have	you been deposed before?				
22	А	At least ten.				
23	Q	At least ten.				
24		Were any of those in patent cases?				
25	A	One.				
		U.S. LEGA				

```
deposed. You were -- I guess, you weren't quite
19
     sure, and I'm not trying to pin you down to a
20
    number.
21
                So the other cases, other than the
    patent case, what type of cases were those?
22
```

Primarily malpractice-related cases,

And then you said a case for Pfizer,

and then I was also involved in a case for Pfizer.

23

24 25

0

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Page 14
                                                                                                            Page 16
 1
    what type of case was the case for Pfizer?
                                                            1
                                                                truthfully; correct?
 2
                Okay. That was an MDL.
                                                                     Α
                                                                           Correct.
 3
                       Was it a product liability-type
                                                            3
                                                                     Q
                                                                           Okay. All right. Let's mark the first
                                                                exhibit.
 4
     case?
 5
                Yeah. The -- the case centered around
                                                            5
                                                                            (Miller Deposition Exhibit 1 was marked
                                                                for identification and attached to the
     the development of diabetes amongst women.
 7
                And in the patent case, the
                                                                transcript.)
    pitavastatin case, were you testifying regarding
                                                            8
                                                                     BY MR. CLEMENT:
 8
9
     infringement?
                                                            9
                                                                           Dr. Miller, what the court reporter has
10
          Α
                Yeah -- yes.
                                                                put before you -- and marked as Miller Exhibit 1,
                What about validity or invalidity?
                                                                is a Defendant's Notice of Deposition of Dr.
11
                Well, as I recall, I was asked to
                                                                Michael Miller.
12
    testify about the method that made the drug -- the
13
                                                                           Have you ever seen this document
14
     compound unique in its class.
                                                               before?
                And what made the compound unique in
                                                                            (Witness reviews document.)
15
                                                           15
16
    its class?
                                                           16
                                                                           I'm not sure that I have.
17
                Well, there are several properties of
                                                           17
                                                                     Q
                                                                           Okay. How did you know to come here
18
    pitavastatin both -- both from a chemical
                                                           18
                                                                today?
19
     standpoint as well as a clinical standpoint that
                                                           19
                                                                     Α
                                                                           Well, I came here today because I've
    was associated with reduced side effects that may
20
                                                           20
                                                                been working on this case with Covington.
21
    have been experienced by patients taking other
                                                           21
                                                                     Q
                                                                           And they informed you that your
22
    medications --
                                                                deposition was going to be today?
                                                           22
23
          0
                So reduced --
                                                           23
                                                                     Α
                                                                           That is correct.
                -- other statins.
                                                                           Okay. You know, this is more a formal
24
          Α
                                                           24
25
                -- reduced drug interactions?
                                                                -- just, you know, take some of the mystery out of
          0
                                                                                                            Page 17
                                                Page 15
1
                That is correct.
                                                                it, this is more of a formal document and why
                Okay. And different from other
                                                                Covington told you -- I'll represent to you at
 3
     statins, it would have reduced side effects; is
                                                                least my belief. It's why Covington told you to
     that what you're --
                                                                appear here today, but that's fine you haven't
 5
          Α
                Correct.
                                                                seen the document.
 6
                -- saying?
                                                                           Did you prepare for your deposition
 7
                Okay. All right. So you've been
                                                                today?
8
    deposed before, so, I quess, you know kind of the
                                                                           I did.
     drill here. I'm going to ask you a series of
                                                                           Okay. And about how long did you
9
                                                            9
                                                                     Q
    questions. You know nods of the head can't be
                                                                prepare for your deposition today?
10
    recorded, so I'd ask for verbal responses, yes or
                                                                           In terms of hours?
11
                                                           11
                                                                     Α
    no if it's a yes/no question.
12
                                                                     Q
                                                                           Days, hours.
13
          Δ
                Yes.
                                                           13
                                                                     Δ
                                                                           I don't have an exact number at this
14
                Is that okay?
                                                           14
                                                                time.
15
                Yes.
                                                           15
                                                                     0
                                                                           Okay. Was it -- did you meet with
                All right. And if you don't understand
                                                                counsel yesterday?
16
          0
                                                           16
17
     the question, please let me know and I'll try and
                                                           17
                                                                     Α
18
    rephrase.
                                                           18
                                                                           How many times did you meet with
19
          Α
                Thank you.
                                                           19
                                                                counsel for prep -- for your deposition
                                                                preparation?
20
                Okay. And is there any reason you
                                                           2.0
21
    can't answer the questions I have today
                                                           21
                                                                     Α
                                                                           For the deposition preparation, I
    truthfully?
                                                               believed -- I believe that I met with counsel
22
                                                           22
23
          Α
                                                           23
                                                                twice.
                                                           24
24
                Okay. You're not on any medications
                                                                           Twice, okay.
                                                                     0
    that would impair your ability to answer
                                                           25
                                                                           And when was that? One was yesterday;
```

		02/15	018 18 to 2.	
		Page 18		Page 20
1	is that c	orrect?	1	Q Do you recall reviewing anything other
2	A	One was yesterday.	2	than what was in your declaration in your meetings
3	Q	And when was the other?	3	with Covington preparing for the deposition?
4	A	Within the past two weeks.	4	A I think I did.
5	Q	And about within the past so	5	Q Okay. Could you recall what documents
6	the le	t's strike that.	6	those were?
7		So the first meeting, the one that	7	A Again, I would have to review my
8	was oc	curred other than yesterday, was that an	8	declaration to see the documents.
9	in-person	meeting or telephone?	9	Q Okay. So none come to mind as
10	A	In person.	10	documents that you did not have as an exhibit to
11	Q	In person.	11	your declaration that you reviewed in preparation
12		And that was at Covington's offices?	12	for your deposition?
13	A	That is correct.	13	A Well, I reviewed Wharton's deposition.
14	Q	And was that a full-day meeting?	14	Q Okay. Did you review his report as
15	A	How do you define "full day"?	15	well?
16	Q	Eight hours.	16	A I reviewed his declaration as well.
17	A	No.	17	Q Declaration, thank you.
18	Q	Okay. Part of a day?	18	Okay. Do you recall any other
19	A	That's correct.	19	documents not exhibits to your declaration
20	Q	Okay. Did it start in the morning?	20	A I don't recall.
21	А	Yes.	21	Q that you reviewed?
22	Q	Go through lunch?	22	Okay. And then yesterday you met with
23	A	Yes.	23	counsel, also?
24	Q	And into the afternoon?	24	A That is correct.
25	A	Early to mid-afternoon.	25	Q Okay. Who did you meet with yesterday?
			-	
	0	Page 19		Page 21
1	Q	Okay. So six hours would be a	1	A I met with Mike Kennedy, Han, Megan
2		e estimate?	2	Keane.
3	A	Yes.	3	Q Anyone else?
4	Q	Did you review documents?	4	A Joe was in the room.
5	A	Yes.	5	Q Anyone else?
6	Q reviewed?	Do you recall what documents you	6	A I believe that's it.
				Q Okay. And was yesterday a full day?
8	A	Primarily the documents related to this	8	A Yesterday was a full day.
9	case.	De com marell objek anago	9	Q Okay. And, again, did you review any
10	Q	Do you recall which ones?	10	documents yesterday in preparation for today's
11	A	My declaration.	11	deposition that were not exhibits to your
12	Q	Any others?	12	declaration?
13	A	The patents, prosecution history.	13	A I don't believe so.
14	Q	All the prosecution histories or any	14	Q Okay. But you might have did you
15	one in pa		15	review Wharton's deposition transcript yesterday?
16	A	As it related to my declaration.	16	A Minimally.
17	Q da all accabi	So in your exhibits to your	17	Q Okay. And what about his
18		on, you had excerpts from the '727	18	declaration his declaration?
19	-	on history and the '728 prosecution	19	A Minimally.
20	history.	There alid you would be able to the	20	Q Okay. Do you recall how you became an
21	+h1	Any did you review other other	21	expert in this case?
22		e two, did you review prosecution	22	A I believe I was contacted by Covington
23	histories		23	sometime last summer.
24	A	I would have to refer to my declaration	24	Q Were you aware that there was a prior
25	to see wn	ich other patents I reviewed.	25	case involving the same drug between Amarin and
			1	

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Page 22
                                                                                                            Page 24
    defendants that was pending in New Jersey a few
                                                            1
                                                                           Okay. Okay. And I think you say in
 2
     years ago?
                                                                this declaration, and correct me if I'm wrong, but
 3
          Α
                No.
                                                                you understand that all of the patents involved in
                                                                this lawsuit except for one, the '594, they all
                So the first time you were contacted by
 5
     Covington regarding working on a Vascepa
                                                                share the same patent specification?
     litigation was last summer?
                                                                     Α
                                                                           Yes.
 7
                That is correct.
                                                                     Q
                                                                           Okay. So it will be okay by you if
 8
                And do you recall who contacted you?
                                                                when we refer to column and line numbers unless I
 9
                I don't.
                                                                indicate otherwise, I'm going to be referring to
10
                Okay. Let's mark your declaration as
                                                                the '728 patent; is that okay?
    Miller Exhibit 2.
                                                                     Α
                                                                           Yes.
11
                 (Miller Deposition Exhibit 2 was marked
                                                                           Okay. And the last time you reviewed
12
                                                           12
                                                                     Q
     for identification and attached to the
                                                                your declaration was yesterday?
13
                                                           13
                                                                           This morning.
14
     transcript.)
                                                                     Α
          BY MR. CLEMENT:
                                                                           This morning. Okay.
15
                                                           15
16
                And Dr. Miller, what I've put before
                                                           16
                                                                           And in reviewing your declaration, did
    you is a copy of your first declaration in this
17
                                                           17
                                                                you note any corrections or revisions that you
18
    case without the exhibits.
                                                                wanted to make?
19
                Can you take a look at page 47 and
                                                           19
                                                                     Α
                                                                           I don't believe so.
20
    confirm that's your signature?
                                                           2.0
                                                                           Okay.
                Yes, this is my signature.
21
                                                           21
                                                                           MR. CLEMENT: All right. Let's mark as
22
                And you signed that on November 1st,
                                                                Miller Exhibit 3 a copy of the materials
                                                           22
23
                                                                considered which was Exhibit 2 to your
          Α
                I did.
                                                                declaration.
24
                                                           24
                                                                            (Miller Deposition Exhibit 3 was marked
25
                                                           25
          0
                Do you know who wrote this declaration?
                                                 Page 23
                                                                                                            Page 25
1
                Well, the declaration was a
                                                                for identification and attached to the
     collaborative effort between my attorneys and
                                                                transcript.)
 3
    myself. The opinions in this declaration are
                                                                     BY MR. CLEMENT:
     mine.
                                                                           Okay. Dr. Miller, can you confirm this
 5
                Who typed it?
                                                                is the materials you considered for your opening
 6
                I have no idea.
                                                                declaration?
 7
                Okay. You did not type it?
                                                                     Α
 8
          Α
                I did not type it.
                                                                     Q
                                                                           And where did you get these materials?
9
                Okay. So drafts went back and forth
                                                                           The majority of the materials were
                                                            9
                                                                     Α
    between you and counsel. You commented on it.
                                                                provided to me by my attorneys.
10
    And this is the final product, and it contains
                                                                           Okay. And did your counsel provide you
11
                                                           11
    your opinions; right?
                                                                any materials to look at that are not on this
12
13
          Δ
                That is correct.
                                                           13
                                                                list?
                                                                           I don't believe so.
14
                Okay. Have you ever been involved in
                                                           14
15
    a -- do you under- -- well, strike that.
                                                           15
                                                                     0
                                                                           Did you do any research to find
                Do you understand that your declaration
                                                                materials?
16
                                                           16
17
    pertains to something called claim construction?
                                                           17
                                                                     Α
                                                                           I didn't do additional research beyond
18
          Α
                Yes.
                                                           18
                                                                what appears here.
19
                Okay. Have you ever been involved in a
                                                           19
                                                                           So all of the materials that are in
                                                                these materials considered Miller Exhibit 3 came
20
    claim construction proceeding before?
                                                           2.0
21
          Α
                No.
                                                           21
                                                                from counsel?
                                                                           Well, I was familiar with a number of
22
          0
                                                           22
23
                So you're -- in the pitavastatin case,
                                                           23
                                                                the publications prior to counsel providing them
    you were not involved in the claim construction?
                                                           24
                                                                to me.
24
25
          Α
                Correct
                                                           25
                                                                     0
                                                                           Did you instruct counsel to find those
```

Okay. But the opinions you provided

24

25

Dr. Wharton's opinions.

0

24

25

Α

0

Yes, it is.

And you signed that on February 2nd,

	Page 30		Page 32
1	related to two terms; correct?	1	prepared? Was this, again, a collaborative effort
2	A In this reply declaration, that is	2	similar to the first declaration?
3	correct.	3	A Yes.
4	Q Okay. And that was the	4	Q Did you know Amarin Pharmaceuticals
5	"concurrent/concomitant lipid-altering therapy"	5	before you became involved in this case?
6	term; that would be one of them?	6	A I did.
7	A That is correct.	7	Q And how did you know Amarin
8	Q And then also the "without	8	Pharmaceuticals before coming becoming involved
9	substantially increasing LDL-C" terms; right?	9	in this case?
10	A That is correct.	10	A They make Vascepa.
11	Q And why did you only choose to put in	11	Q Okay. Any other way?
12	your reply declaration responses regarding those	12	A They contacted me to serve on the
13	two terms?	13	steering committee for a clinical outcome study.
14	A To provide clarification.	14	Q Any other ways?
15	Q And you didn't think any further	15	A That was our initial that was how we
16	clarification was required for the other terms	16	made contact.
17	that Dr. Wharton opined on?	17	Q Okay. But did they have you been
18	A Well, not necessarily, but this	18	involved with Amarin other than and outside the
19	these were the most important claim terms that I	19	scope of this case, have you been involved with
20	wanted to comment on.	20	Amarin other than as the steering committee on a
21	Q Okay. And you didn't feel the need to	21	clinical outcome study?
22	comment on the other terms that Dr. Wharton opined	22	A Yes.
23	on; correct?	23	Q In what way or ways?
24	A That's correct.	24	A They they asked me to give a
25	Q Do you know how these two terms were	25	presentation at the EMDAC meeting on
1	Page 31 selected? Did you select these two terms or did	1	Page 33 triglycerides.
1 2			
	selected? Did you select these two terms or did	1	triglycerides.
2	selected? Did you select these two terms or did counsel?	1 2	triglycerides. Q Any other ways?
2 3	selected? Did you select these two terms or did counsel? A I did not select the claim terms.	1 2 3	triglycerides. Q Any other ways? A I advise them.
2 3 4	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further	1 2 3 4 5	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them?
2 3 4 5	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy"	1 2 3 4 5	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily
2 3 4 5 6	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms?	1 2 3 4 5 6	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily as it relates to REDUCE-IT.
2 3 4 5 6 7	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms? MR. KENNEDY: I caution the witness	1 2 3 4 5 6 7	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily as it relates to REDUCE-IT. Q Is REDUCE-IT different than the
2 3 4 5 6 7 8	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms? MR. KENNEDY: I caution the witness the witness can answer that question yes or no,	1 2 3 4 5 6 7 8	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily as it relates to REDUCE-IT. Q Is REDUCE-IT different than the clinical outcome study you referred to?
2 3 4 5 6 7 8	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms? MR. KENNEDY: I caution the witness the witness can answer that question yes or no, but I caution the witness to avoid revealing the	1 2 3 4 5 6 7 8 9	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily as it relates to REDUCE-IT. Q Is REDUCE-IT different than the clinical outcome study you referred to? A That is the clinical outcome study.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	selected? Did you select these two terms or did counsel? A I did not select the claim terms. Q So counsel asked you to opine further on "concurrent/concomitant lipid-altering therapy" and the "without substantially increasing" terms? MR. KENNEDY: I caution the witness the witness can answer that question yes or no, but I caution the witness to avoid revealing the substance of communications he may have had with counsel. BY MR. CLEMENT: Q Yes or no is fine. A Can you repeat the question, please? MR. CLEMENT: Can you read that back? (The Record was read as requested.) THE WITNESS: Yes. BY MR. CLEMENT: Q And when was the last time you reviewed your reply declaration, Miller 4? A Within the past 24 hours. Q And, again, do you have any corrections or revisions you want to make on this exhibit?	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	triglycerides. Q Any other ways? A I advise them. Q So you serve as a consultant for them? A Yes, I serve as a consultant primarily as it relates to REDUCE-IT. Q Is REDUCE-IT different than the clinical outcome study you referred to? A That is the clinical outcome study. Q And you say "primarily," you consult with them primarily as to REDUCE-IT. Do you consult with them as to other? A I've worked with them to provide training for physicians. Q And can you be a little bit more specific? How do you work with them to provide training for physicians? A They they have a as with other pharmaceutical companies, they have a a platform where potential speakers will discuss in a disease-management-fashion triglyceride lowering, the importance of triglycerides, and I've helped to build on that foundation.

Case 2:16-cv-02525-144120-NJKi-10-00cm entD119-3 Filed 04/17/18 Page 11 of 72 02/15/2018 34 to 37 Page 34 Page 36 It -- it -- it's really more for 1 Q -- you recall when? 2 teaching physicians about management of Α Within the last six months. triglycerides. So teaching the physicians who 3 And the attendees at these meetings are just you and Amarin or are other people attending? will go out and perform these activities. 4 5 Right. The attendees at these meetings are 6 But, I guess -physicians, generally, who are interested in 7 So I don't -- I don't -- I don't speak treating lipid disorders. Many of them are for Amarin, but I've advised them on teaching certified by the National Lipid Association. 9 other physicians. 9 So these are individuals who have 10 Okay. So you were -- how they would go 10 familiarity and are accustomed to seeing patients and teach other physicians. with lipid disorders. 11 12 Is it for their sales reps? I mean, 12 And do you speak at these -- I guess I'm just trying to understand. I'm a little con- -- I'm trying to understand 13 13 14 No, it's other physicians in -- in the better. I can't recall. Did you say you -- do field and essentially providing educational you speak to these physicians at these outside 15 16 information. venues we just discussed? I speak to the physicians; that is 17 So is this something that takes place 17 Α 18 at Amarin's facilities, or is it at a --18 correct. 19 Does not take place --19 0 Are you on, like, a panel? 20 -- different location? 2.0 Α Yes. 21 Α Does not take place at Amarin's 21 Ω Okay. Do you recall who else was on 22 facilities. 22 the panels with you? Let's take the California 23 0 Okay. Does this take place off-site 23 one. somewhere -- some -- give me -- can you -- I Α There -- there were a few that I -- I'd 24 24 guess -- strike that. 25 have to go through the NLA review to take -- take Page 35 Page 37 1 Can you give me an example of where a look at that. this would take place? Okay. Do you recall who was in the 3 Yeah, it takes place -- it's Florida one -- six months ago? basically -- it could take place at a -- at an Α Again, I would have to look at the outside venue. 5 review. 6 Okay. You also said you gave a 7 Do you recall any outside venues where presentation to EMDAC as part of some of the other 8 it did take place? consulting work you do for Amarin; is that 9 There was a conference that took place correct? 9 in California. 10 Α That was about five years ago. 10 What is EMDAC? 11 Okay. Do you recall when that was and 11 Ω where in California? It is a -- an FDA endocrinology 12 Α committee that -- that is assigned to review, I 13 That was about a year ago. 13 And where in California? 14 guess, companies who are looking to seek a change 15 San Diego. 15 either in -- a new label or a change in a label, Okay. Can you recall any other 16 an indication for their compound. 16 0 17 examples of these meetings that took place at 17 Okay. So we've talked about your 18 outside venues? serving on the steering committee for the 19 Δ There was one in Florida. 19 REDUCE-IT study; right? 2

20	Q	Any others?	20	A Yes.
21	A	That's it.	21	Q We talked about the EMDAC EMDAC
22	Q	Okay. And where in Florida and when?	22	meeting that you attended and also the California
23	A	South Florida.	23	conference and Florida conference.
24	Q	Okay. And do	24	A Correct.
25	A	Within	25	Q Any other work for Amarin?

Page 38 Page 40 1 Α 1 BY MR. CLEMENT: 2 Q Okay. Do you get paid for your work on And Dr. Miller, what the court reporter 3 the steering committee? has placed in front of you I'll represent to you is a copy of the CV that you attached to your 4 Α Yes. 5 Do you get paid for your work at -- at initial declaration in this case as Exhibit 1. the EMDAC meeting? Can you just take a quick look and --7 I did, yes. Α Well, I believe it was Exhibit 5. 8 And do you get paid for your work when Right. It is Exhibit 5, but I believe 9 you attend -- attended the California -- on the it was Exhibit 1 to your declaration. It is 10 panel at the California conference? Exhibit 5 here, yes. 11 11 Α Got it. And also at the Florida conference? 12 I think we're going to get a little 12 confused with the exhibit numbers. 13 13 14 Q Do you recall about how much you've (Witness reviews document.) been paid by Amarin for this work? Okay. Do you know when this is 15 15 Q 16 Α I don't. 16 up-to-date as of -- as of when? 17 Okay. So when you're at these 17 Α It says November 2017. 18 conferences, do you advise the physicians to 18 0 Okay. Is there any additions or 19 prescribe drugs -- any drugs? 19 revisions? 20 I don't. 2.0 Α I think paper 160 has been published. 21 You don't advise them to prescribe 21 Ω And what page is that on? 22 Vascepa if the patient presents in a certain 22 Α That is page 35. 23 manner? 23 Okay. Any other revisions or 0 24 I don't. supplementations? Α 24 25 25 No, I don't believe so. 0 Okay. Do you present on -- I guess --Α Page 39 Page 41 can you give me an example of what you present on? Okay. If you'll turn to page 7 of this 2 Α Sure. Miller Exhibit 5, you have there in 2012 an entry 3 I -- at the most recent meeting, I saying that you were on the international steering talked about treating high risk patients and the committee, Amarin: REDUCE-IT trial; correct? areas that have not received attention as much. Α That's correct. 6 So the talk focused on LDL centricity, that is, Okay. And that's what we talked about 7 treatment of patients with high LDL specifically. earlier? 8 Another part of the treatment --Α Yes. another part focused on treatment of inflammation; 9 Okay. And that was the clinical 9 another part focused on diabetes. outcomes -- you referred to it as the clinical 10 11 When you say "LDL centricity," what do 11 outcomes trial? 12 you mean by centricity? Α 13 Yeah. So there are some that believe 13 0 And what was that clinical trial about? 14 that all you need to do to treat a patient with 14 Well, the -- the trial is still 15 heart disease with respect to treatment of lipid 15 ongoing, and it's about examining whether patients disorders -- lipid disorders, quote/unquote, is to that have hypertriglyceridemia with cardiovascular 16 16 17 put them on a statin to lower LDL and nothing else 17 disease may reduce their risk with ethyl 18 really matters. So it is an LDL-centric focus. 18 eicosapentaenoic. 19 Gotcha. Okay. Thank you. 19 MR. CLEMENT: We'll get you the 20 MR. CLEMENT: Okay. Let's mark the 20 spellings after. 21 next exhibit which is a copy of your CV, and 21 BY MR. CLEMENT: that's Miller 5; correct? Is that -- are you still serving on 22 22 0 23 (Miller Deposition Exhibit 5 was marked 23 that steering committee then? for identification and attached to the 24 24 Α T am. 25 transcript.) 25 0 How -- how -- I guess, how much work

02/15/2018 42 to 45 Page 42 Page 44 does that involve? I mean, how -- in the last 12 1 MR. KENNEDY: Okay. 2 months, how much time have you spent? BY MR. CLEMENT: 3 We have teleconferences quarterly. REDACTED And you get paid for that work; Q 5 correct? 6 Α I do. 7 Do you recall how much? 8 I don't, but it's -- it's modest. 9 And you've been serving on this 10 REDUCE-IT steering committee since 2012? 10 What does retention mean? 11 Α Α Retention is -- is keeping or trying to And what does it -- I guess, what do maintain a subject in a clinical trial. What 12 you do as a member of the steering committee for sometimes happens is patients may move, so we need 13 13 the REDUCE-IT trial? to try to find another site for them. Things REDACTED 15 happen. 16 0 Uh-huh. 17 Α So we try to maintain as many of our 18 patients in the study until trial end. 19 Okay. 0 2.0 MR. CLEMENT: Let's mark as the next 21 Okay. And -- is that -- you're still 21 exhibit Miller 6, a copy of some email 22 discussing that in steering committee meetings 22 correspondence. 23 today or has it evolved over the -- what is it --23 (Miller Deposition Exhibit 6 was marked five or six years that you've been involved? for identification and attached to the 24 24 REDACTED transcript.) Page 43 Page 45 REDACTED BY MR. CLEMENT: Dr. Miller, I guess, have you ever seen this document before? It looks like I have. And would you agree with me that it's a copy of some email correspondence between you and Paresh Soni? Α Correct. And there's three emails on the page? 9 0 10 Α Who is Paresh Soni? Paresh Soni was -- is a physician who Α worked with Amarin and -- on -- on this compound and was involved in -- in the REDUCE-IT clinical trial. 0 Now, this is dated 2010; right? 16 17 MR. KENNEDY: Let me just state I'd 17 Α 18 like a -- if you're going to get deeper into it, I So were you working on the REDUCE-IT 19 would like a chance to consult with my client 19 trial before you were a member of the steering 20 about the exact contours of his confidentiality 20 committee? 21 obligation. Sitting here today, I'm not sure it's 21 Α No. No, I -- the -- the -- the covered by the litigation protective order. basic premise of this email was when I was 22 23 MR. CLEMENT: That's fair. I don't 23 originally contacted by Paresh, I was involved think I'm going to get too deep into it. I 24 24 in -- in writing an American Heart Association 25 just . . . statement, and, so, it was unclear whether or not

Page 46 Page 48 I could participate in -- in -- in working with Q Okay. Do you know who B. Stirtan is? I believe he worked with Amarin at that 2 on this committee. Α 3 So I had to go through my channels at time. the American Heart Association as well as the And R. Braeckman? Q National Institutes of Health, and as stated in 5 Α Yeah, that's Rene Braeckman. He and that March 4, 2010 email, that I had been cleared Paresh were -- were, I believe, on the invention 7 to -- to work with Paresh and the Amarin team. of -- of many if not all of the patents. 8 Okay. So this was before you were on Do you consider them experts in the 9 the REDUCE-IT steering committee; right? 9 field, Paresh and Rene Braeckman? 10 Correct. 10 Well, I consider them experts with And the outcome study that is referred respect to this particular compound, but if you 11 to in the very bottom email, that would be the could clarify what you mean by "experts" -- in 12 REDUCE-IT study? what field. 13 13 14 Α That is correct. 14 Q Lipidology. Α Yeah, Paresh, I believe, was an M.D. 15 And in the top email Paresh says the 15 16 first step is to execute the consulting agreement. Ph.D., so I -- but I'm not sure his clinical involvement. But -- but certainly he had a pretty 17 Do you see that? 17 18 Α I do. good knowledge base. If he was not seeing 19 Do you recall executing the consulting patients, then I would -- I would think that he 0 20 agreement? would consult with those that do, same with Rene. 21 Α I -- I must have. 21 Would you consider them -- I quess, in 22 Okay. And would that have been 22 this case you recall you gave a definition of a 23 pre-serving on this steering committee for 23 person of ordinary skill in the art. REDUCE-IT? (Witness nods head.) 24 24 Α 25 Α Yes. 25 Would you consider Paresh Soni to meet 0 Page 47 Page 49 1 Do you recall -- have you got paid for that definition? that consultant -- consultancy? MR. KENNEDY: Objection to form. 3 Well, I've been paid. It's -- it's 3 THE WITNESS: I don't know that I been the same agreement once I entered into the would. REDUCE-IT team or I should say steering committee. BY MR. CLEMENT: 5 6 Okay. What about Rene Braeckman? 7 MR. CLEMENT: Let's mark the next Α I don't --8 exhibit. It's Miller 7. MR. KENNEDY: Same objection. 9 (Miller Deposition Exhibit 7 was marked 9 THE WITNESS: I don't know that I for identification and attached to the would. 10 transcript.) BY MR. CLEMENT: 11 11 BY MR. CLEMENT: 12 12 Q Okay. Why don't you know that you 13 And, Dr. Miller, I put some draft notes 13 would? 14 dated March 24, 2010, in front of you. 14 Well, because in my opinion a person of ordinary skill in the art as it relates to this 15 Have you ever seen these before? 15 Α I don't recall. particular field is a clinician who has pretty 16 17 Do you see the header for the exhibit, 17 extensive experience in treating lipid disorders, 18 Miller 7? It says, Meeting with Michael Miller and I -- I don't know the extent to which either 19 University of Maryland School of Medicine? 19 of these individuals do. 20 Α 20 Okay. And when you say "a person of 21 Ω And attendees M. Miller, P. Soni, B. 21 ordinary skill in the art as it relates to this Stirtan, and R. Braeckman? 22 22 particular field," how do you define that field? 23 Α Yes. 23 The field of very high triglycerides; 24 Q That Michael Miller is you; right? 24 that's VHTG. These are triglycerides at or 25 Δ That is me. exceeding 500 milligrams per deciliter -- to

		<u> </u>	720		50 to 53
		Page 50			Page 52
1	distinguish	n it from patients that come in after a	1	Q	So that would be a different outcome
2	cardiac eve	ent that a cardiologist will prescribe a	2	study than	n the REDUCE-IT?
3	statin for.		3	A	Yes.
4	Q	Okay. In this email he talks about	4	Q	They also refer here to a Roche:
5	a you we	ere not able to join Amarin at a	5	dal-OUTCOM	MES.
6	February 27	th ad board meeting.	6		Do you know what that is?
7		Do you see that?	7	A	I do.
8	A	Yes.	8	Q	What is that?
9	Q	Do you know what an ad board meeting	9	A	Dal-OUTCOMES was a clinical outcome
10	is?		10	study look	ring at cholesteryl ester transfer
11	A	I don't know how it was used within	11	protein or	or CETP inhibitor that at that time was
12	this contex	tt. Ad board meetings can mean a lot of	12	ongoing.	
13	things. It	can mean anything from putting	13	Q	And what about the AIM-HIGH study?
14	together th	me clinical trial for all I know.	14	A	The AIM-HIGH study was another clinical
15	Q	Do you recall being on an ad board for	15	trial look	king to determine if raising HDL with
16	Amarin?		16		top of standard of care therapy that
17	A	Well, as I said, I serving I	17		statin therapy would reduce
18	would view	myself as serving in the capacity of an	18		cular risk.
19		virtue of being on the steering	19	0	And then it refers to a Bill Stanley?
20	_	for REDUCE-IT. That would constitute	20	~ A	This is my colleague who died.
21	advising.		21	0	Oh, okay.
22	aa.121119.	So, yes, ad board could be used	22	×	Then the next category here is EPA
23	interchange		23	versus DHA	A Discussion.
24	Q	Okay. Great.	24	101505 511	Do you see that?
25	×	And then they it looks like here	25	А	I do.
					1 40.
1		Page 51	1		Page 53
1	that they o	Page 51 lid consult with you on March 24th even	1	Q	Page 53 Was that something you were involved
1 2	_		1 2	Q in?	
	_	did consult with you on March 24th even		-	
2	though you	did consult with you on March 24th even	2	in?	Was that something you were involved
2 3	though you meeting?	lid consult with you on March 24th even weren't able to join that February 27th	2 3	in? A discussion	Was that something you were involved I don't recall we may have had
2 3 4	though you meeting?	did consult with you on March 24th even weren't able to join that February 27th I believe they came to Baltimore.	2 3 4	in? A discussion	Was that something you were involved I don't recall we may have had as about it, but and I I remember ask produced DHA, but I don't recall much
2 3 4 5	though you meeting? A Q A	Idd consult with you on March 24th even weren't able to join that February 27th I believe they came to Baltimore. So you recall that meeting?	2 3 4 5	in? A discussion that Marte	Was that something you were involved I don't recall we may have had as about it, but and I I remember ask produced DHA, but I don't recall much
2 3 4 5 6	though you meeting? A Q A also met wi	Note that the venture of the venture	2 3 4 5 6	in? A discussion that Marte	Was that something you were involved I don't recall we may have had as about it, but and I I remember ek produced DHA, but I don't recall much and that.
2 3 4 5 6 7	though you meeting? A Q A also met wi	Weren't able to join that February 27th I believe they came to Baltimore. So you recall that meeting? I I I do because we had they that colleague of mine who then died	2 3 4 5 6 7	in? A discussion that Marte	Was that something you were involved I don't recall we may have had as about it, but and I I remember ek produced DHA, but I don't recall much ad that. And it says here, Thoughts on MOA for
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	though you meeting? A Q A also met witragically Q board slide outcome sturecollection A recall is w Q the general A Q A	Idid consult with you on March 24th even weren't able to join that February 27th I believe they came to Baltimore. So you recall that meeting? I I I do because we had they the a colleague of mine who then died subsequently. It was very unfortunate. Sorry to hear that. And it says P. Soni presented the ad edeck and Rene Braeckman reviewed the eddy synopsis. Do you remember do you have a en of what that ad board slide deck was? I I have no idea. What what I do be discussed the REDUCE-IT study. Okay. Now, they also talk here under comments about a GSK outcome study. Do you see that? I do. Is that a different outcome study? So GSK was in the process of putting	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in? A discussion that Marte more beyon Q LDL increa understand A Q talks about considerat A Q A That is the became Vas Q easier for A	I don't recall we may have had as about it, but and I I remember ek produced DHA, but I don't recall much ad that. And it says here, Thoughts on MOA for ase by DHA. Do you have any do you have an aling of what MOA means? Mechanism of action. Okay. Then the next part of the email at the AMR101 outcome study cions. I see that. What do you know what AMR101 is? That's the ethyl eicosapentaenoic. The compound that was used before it scepa. Okay. Can we say icosapent to make it the court reporter? Sure.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	though you meeting? A Q A also met witragically Q board slide outcome sturecollection A recall is w Q the general A Q A together ar	Idid consult with you on March 24th even weren't able to join that February 27th I believe they came to Baltimore. So you recall that meeting? I I I do because we had they the acolleague of mine who then died subsequently. It was very unfortunate. Sorry to hear that. And it says P. Soni presented the ad edeck and Rene Braeckman reviewed the day synopsis. Do you remember do you have a can of what that ad board slide deck was? I I have no idea. What what I do not discussed the REDUCE-IT study. Okay. Now, they also talk here under comments about a GSK outcome study. Do you see that? I do. Is that a different outcome study? So GSK was in the process of putting a outcome study with Lovaza.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	in? A discussion that Marte more beyon Q LDL increa understand A Q talks about considerat A Q A That is the became Vass Q easier for A Q	I don't recall we may have had as about it, but and I I remember ek produced DHA, but I don't recall much and that. And it says here, Thoughts on MOA for ase by DHA. Do you have any do you have an aling of what MOA means? Mechanism of action. Okay. Then the next part of the email at the AMR101 outcome study cions. I see that. What do you know what AMR101 is? That's the ethyl eicosapentaenoic. The compound that was used before it scepa. Okay. Can we say icosapent to make it the court reporter? Sure. Okay. Then it talks about some
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	though you meeting? A Q A also met witragically Q board slide outcome sturecollection A recall is w Q the general A Q A	Idid consult with you on March 24th even weren't able to join that February 27th I believe they came to Baltimore. So you recall that meeting? I I I do because we had they the a colleague of mine who then died subsequently. It was very unfortunate. Sorry to hear that. And it says P. Soni presented the ad edeck and Rene Braeckman reviewed the eddy synopsis. Do you remember do you have a en of what that ad board slide deck was? I I have no idea. What what I do be discussed the REDUCE-IT study. Okay. Now, they also talk here under comments about a GSK outcome study. Do you see that? I do. Is that a different outcome study? So GSK was in the process of putting	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in? A discussion that Marte more beyon Q LDL increa understand A Q talks about considerat A Q A That is the became Vas Q easier for A	I don't recall we may have had as about it, but and I I remember ek produced DHA, but I don't recall much and that. And it says here, Thoughts on MOA for ase by DHA. Do you have any do you have an aling of what MOA means? Mechanism of action. Okay. Then the next part of the email at the AMR101 outcome study cions. I see that. What do you know what AMR101 is? That's the ethyl eicosapentaenoic. The compound that was used before it scepa. Okay. Can we say icosapent to make it the court reporter? Sure. Okay. Then it talks about some

54 to 57 Page 54 Page 56 1 Is that something you talk about when large the study was null, the clinical trial was 2 you're on the recruitment phase on the steering null, with the exception of the 3 committee as what patients to include, what hypertriglyceridemia, low HDL subgroup. inclusion criteria to have? And there it was shown to be effective? 4 4 5 This actually proceeded that, so this 5 Α These were post hoc analyses, so was a discussion as to what the entry criteria they're what we refer to as hypothesis generating. 7 should be when the study was formalized. And, therefore, it wasn't shown because the study 8 Okay. Were you involved in these wasn't designed to specifically evaluate it, but 9 discussions on what the inclusion criteria should it raised the suggestion that if you focused 10 another trial on a patient population with high 11 I think they asked my -- I'm presuming TG, for example, that you may have a different that they asked my opinion back -- as these notes outcome. 12 relate to --13 13 0 Different outcome meaning it would have been effective? 14 Th-huh. Α Well, we don't know. 15 Α -- but beyond that I -- I don't recall. 15 16 And do you see under the TG entry level 16 0 Right. But that would have been the there's a little Roman numeral II? 17 17 hypothesis? 18 18 Α That's why Amarin stepped up to the 19 0 And it talks about a 15 percent leeway plate to do the trial. 19 20 in triglyceride measure to enroll patients at 2.0 Q The --21 either end of the range? 21 Α First --22 Α 22 0 -- trial on fibrates? Yes. 23 0 I guess -- do you know what that 23 The first -- Amarin was the first 15 percent refers to? company to do a clinical trial specifically 24 24 25 Variability. 25 evaluating this high risk group. Α Page 55 Page 57 1 Q But, so, was that 15 percent above or 1 So essentially Abbott turned it down, below 500? GSK turned it down, but Abbott went up to the 3 Α Either -- either way. plate and took the risk to do the study, and that Either way. study is called REDUCE-IT. So it could be 15 percent above 500? 5 Okay. I think you said Abbott. You 5 6 I think it was at the lower limit. The meant Amarin; right? 7 discussion was more focusing on 150. Amarin came -- stepped up to the plate; 8 Ω Okay. So that was 15 percent above or that is correct. below the 150? But this is referring to fibrates; 9 9 Q I believe so. right? 10 Not the 500? Correct. 11 11 Α And the --12 Α 12 Q 13 Going down to the risk factors, do you 13 Α Fibrates were the -- the study for 0 14 see there's a reference to post-ACS patients? fibrates was a Abbott study. 15 Α 15 And the post hoc analysis you were 0 Do you know what that refers to? referring to was looking at what the hypothesis 16 16 17 Α A post-ACS is after an acute coronary 17 would be for fibrates or for icosapent? 18 syndrome. 18 For a -- a medicine that would lower 19 0 Then if we turn down to fibrates at the 19 triglyceride which fibrates lower triglyceride, bottom. It says, Fibrates are in trouble except but in the studies that had been done, they did 2.0 2.0 21 for high TG, low HDL population. 21 not hone in or focus specifically on a Α 22 Yes. 22 hypertriglyceridemia population. Okay. And then below that is TPP 23 Ω Do you know what that refers to? 23 Q It -- it refers to the clinical trials feedback. 24 Α 24 25 that had looked at fibrates and found that by and Do you see that?

Page 60 Page 58 1 Α I don't know what TPP is. 1 Α Right. Right? 2 Q Okay. So just going back to the Q 3 fibrates and the post hoc analysis, is that Α It's what I would refer to as because in a clinical study you have to define 4 concomitant lipid-lowering therapy/concurrent 5 what you're looking for before the study occurs lipid-lowering therapy -and looking at things afterwards can have bias? Okay. 7 MR. KENNEDY: Objection to form. Α -- combination. 8 THE WITNESS: That's actually not true. Okay. 9 What -- what happened with the -- the 9 MR. KENNEDY: You okay? Do you need a 10 study for the Abbott sponsored trial known as 10 break? 11 ACCORD, it was not -- Abbott provided the 11 THE WITNESS: I'm fine. medication, but it was an N- -- it was an NHLBI 12 MR. CLEMENT: Let's mark as Miller 8, a 12 study, National Heartland Blood Institute study. document with the Bates number -- I'm sorry. I 13 14 And even though I was not involved in should have been -- have been reading these -putting together the study, some of my colleagues 2739796. 15 were. And they asked NHLBI to focus in on a 16 16 (Miller Deposition Exhibit 8 was marked diabetic population with hypertriglyceridemia, and for identification and attached to the 17 17 18 NHLBI said no. They turned them down. transcript.) 19 Hence the intention was there to do the 19 BY MR. CLEMENT: 20 proper study. It didn't get done. But they were 20 Okay. Dr. Miller, I've put before you 21 able to get in in the study a prespecified 21 what looks like an invoice to me, Miller 22 endpoint which looked at the hypertriglyceridemia, 22 Exhibit 8. 23 low HDL subgroup. 23 Can you identify this for the record? 24 Yes, it's Exhibit 8. It is to Paresh So when the study was over even though 24 Α 25 the results were negative -- no surprise to many in regard to my consulting time for Amarin. Page 61 Page 59 of us -- they did have that prespecified endpoint 1 And this is for the time period of the hypertriglyceridemia, low HDL subgroup and September through December 2010? 3 within that group that was positive. That is correct. 4 So, therefore, that led to Amarin REDACTED 5 stepping up to the plate to do the REDUCE-IT 6 trial. And this is before serving on the 7 BY MR. CLEMENT: steering committee for REDUCE-IT; is that correct? 8 But that positive finding, right, on I believe at this time I was on the this other endpoint, not the primary endpoint, but steering committee. 9 9 that other endpoint, that was based on patients 10 Even though on your CV it says 2012 and 10 taking fibrates? this is 2010 work, you think you started the 11 11 steering committee work earlier? 12 So the way the ACCORD study was 12 13 devised -- is that diabetic patients with vascular 13 Yeah, because the -- I was approved by 14 disease were assigned to LDL-lowering therapy. the American Heart Association and the NIH. 15 they all had to be on a statin and on top of that 15 go back to Exhibit 6, it looks like in March of half the group was randomized to also receive the 16 2010 --16 17 Abbott compound, the fibrate. 17 Q Uh-huh. -- at which time I signed the 18 And the results here -- so the study 18 Α 19 was not powered sufficiently to -- to hone in on 19 consulting agreement, and then, I guess, we were 20 the hypertriglyceridemia, low HDL group, but the 20 in the process of finalizing the REDUCE-IT study. And, so, this would reflect that. 21 results -- certain -- trended in favor of benefit amongst those -- amongst that subgroup. REDACTED 22 23 Ω Taking the fibrate? 24 Α Taking the combination. 25 \cap Combination of fibrate and statin.

		/2018 62 to	
	Page 62 REDACTED	Page REDACTED	64
8 9 10 11 12 13 14 15 16 17 18 19	MR. CLEMENT: Let's mark the next one. And this is going to be Miller 9, Bates number 2769565. (Miller Deposition Exhibit 9 was marked for identification and attached to the transcript.) BY MR. CLEMENT: Q Dr. Miller, can you identify for the record what Miller Exhibit 9 is? A This exhibit, again, is to Paresh regarding my consulting time between January and June of 2011. REDACTED	MR. CLEMENT: Let's mark Miller 11, and document with Bates number 1077327. (Miller Deposition Exhibit 11 was marked for identification and attached to the transcript.) BY MR. CLEMENT: Q And, Dr. Miller, have you ever seen this document before? A I see it now. Q Okay. And this is another invoice the you sent to Amarin? A Yes. Q For the time period I guess, for the different time periods; right? A That's correct. Q One is for November 1 through	hat
	Page 63 REDACTED	Page 1 December let's take it from the top. 2 The first one is for July through 3 October 31, 2011; right?	65
4 5	MR. CLEMENT: Okay. Let's mark the next one. Let's mark this Miller 10, a document	4 A Correct. REDACTED	
6 7 8 9 10	with the Bates numbers 3121925 through 3121931. (Miller Deposition Exhibit 10 was marked for identification and attached to the transcript.) BY MR. CLEMENT: Q Okay. Dr. Miller, have you ever seen	7 Q And then the next period is November 8 through December 16, 2011. 9 A Right. All related to REDUCE-IT. T 10 is correct. REDACTED	1 hat
11 12 13 14 15 16 17 18	this document before? A I do not believe I have. Q Okay. If you can just turn to the page with the Bates number 3121930., I guess, before turning there, this is a document that's talking about Amarin and the REDUCE-IT study in 2014.		
19 20	Do you see that? A I do. REDACTED	19 Q again? 20 Have you ever, sir I guess, have y 21 ever heard the term "KOL"? 22 A I've heard I've heard of it. I 23 don't know what it means. 24 Q Key opinion leader. 25 A Oh, okay.	you

Page 68 Page 66 marked for identification and attached to the 1 Q Have you heard of that? 2 Α Now I have, yes. transcript.) 3 0 Okay. Have you ever served as a KOL 3 BY MR. CLEMENT: Oh, I need to give it to you. Okay. 4 for Amarin? 5 Well, I guess not in the sense that I And, Dr. Miller, have you ever seen think of a key opinion leader. What this document before? 7 pharmaceutical companies have done in the past and 7 Α I do not believe so. I don't know because things have changed over --You're not listed on the emails; right? 8 0 9 over the years, but key opinion leaders could vary 9 Α (Witness shakes head.) 10 between companies, and oftentimes a key opinion 10 Although it does talk -- it does 0 leader might be asked to do -- to do speaking note -- it says, Please note that Doctors Miller, 11 engagements. Weintraub and Nissen are not involved in the 12 But in this particular case, this was trials. And it's giving a contact list for some 13 13 14 related to serving on a committee for a clinical 14 KOLs. 15 15 Α I see that. 16 0 And forgive me if I misled you. I'm 16 Do you know who -- Paresh Soni, we have talked about; correct? 17 not speaking about that exhibit anymore. 17 18 I'm just asking have you ever served as 18 Α 19 a kay -- key opinion leader for Amarin in any 19 0 Do you know who this Martina 20 context? 20 Schwarzkopf is? 21 Α I -- I'm not sure what that means, what 21 Α the context you're referring to is. 22 0 Do you know who David Schull is? 22 23 Who do you currently interact -- so 23 Α I do not. you're still working in some sort of Or Elliott Fox? 24 24 Ω 25 consultancy -- consultancy capacity for Amarin; 25 Α I do not. Page 67 Page 69 right? Q Or Russo Partners? 1 2 Right. I consider myself a member of Α I do not. 3 the steering committee for the REDUCE-IT trial --Okay. If you turn to the attachment, do you see you're listed there -- I guess this is Α -- and advise them accordingly. their -- their list of key opinion leaders. 5 6 0 And who do you interact with at Amarin Do you see that? 7 currently? 7 Α I see the list. 8 A gentleman by the name of -- of Ralph Ω Okay. And your name is on that list? 9 Doyle. 9 Α And do you see a guy named John Kas- --10 0 Anyone else? Kastelein? 11 There are others. I just don't 12 remember all their names. 12 Α Yes. 13 Okay. Do you remember any others, as 13 0 Do you know who he is? 0 14 you sit here today? 14 Α Yes. 15 Α No, but if you gave me a list of names, 15 Okay. Would you consider him to be a I could probably point them to you. person of ordinary skill in the art as you've set 16 17 If I had a list, I -- we'll see. 17 forth in your opinions in your declaration? we -- as we go through, if something comes to your 18 Yes. 18 Α 19 mind, you know, just let me know, please. 19 0 How about as an expert in the field? 20 MR. CLEMENT: Okay. Let's mark the 20 Α Yes. 21 next exhibit which will be Miller 12, a document 21 MR. KENNEDY: Object. with Bates range 1638777 through -- it's 877 BY MR. CLEMENT: 22 22 23 and -- and through 8778, but there's also 23 Ω And what about Harold Bays. Do you attach- -- an attachment. 24 24 know who that is? 25 (Miller Deposition Exhibit 12 was 25 Δ Yes

	02/15	/ 2	70 0 73
1	Page 70 Q And would you consider him to be a	1	Page 72 them to me.
2	person of ordinary skill in the art?	2	A general cardiologist does not
3	A Yes.	3	typically see these patients.
4	Q And an expert?	4	Q Okay. So when you say, "including
5	A Yes.	5	hypertriqlyceridemia," that's a act that's
6	Q And what about James McKenney? Do you	6	actually a requirement for your person of ordinary
7	know who that is?	7	skill in the art. They actually they have to
8	A Yes.	8	have that. It's in a it's a requirement when
9	Q And would you consider that person to	9	you say "including"?
10	be a at least meet the standards of a person of	10	A Well, again, to make them a more
11	ordinary skill in the art as you've defined it?	11	more reputable in field, you have to have
12	A I don't believe that Jim sees patients,	12	experience in in treating whatever whatever
13	so I'm not as sure about that.	13	your you're determining you're titled to.
14	Q Okay. What about Steven Nissen?	14	Very high triglycerides are relatively
15	A Yes, I know him.	15	uncommon. They're not it's not a
16	Q Okay. Would you consider him to at	16	bread-and-butter patient that a cardiologist sees
17	least be a person of ordinary skill in the art as	17	that had that a cardiologist would simply place
18	you defined it in your declaration?	18	a person on a statin and say, you know, I treat
19	A Well, again, I don't know he's a	19	patients with lipid disorders. That this is a
20	cardiologist. I don't know how many patients he	20	little bit different.
21	really sees with VHTG. It's important to to	21	Q Okay. Again, I'm just asking a
22	make a distinction because cardiologists, as a	22	question. I understand your position there.
23	general rule, do not treat patients with VHTG.	23	Is it a requirement when you say,
24	There are exceptions. I'm one of the	24	"including severe hypertriglyceridemia," is that a
25	exceptions, but I have colleagues that are	25	requirement for your person of ordinary skill in
	chooperons, suc I have correspond that are	23	requirements for jour person of ordinary shiff in
1	Page 71 cardiologists that also see them. But by and	1	Page 73 the art, that they are treating patients
2	large VHTG, because because of its relative	2	specifically with hypertriglyceridemia?
3	rarity and the fact that it's not viewed as	3	A Yes, I think they have to have some
4	strikingly associated with cardiovascular disease,	4	experience in this field, absolutely.
5	is generally not seen by cardiologist.	5	Q When you say "some experience," what
6	Q Okay. If you turn to your declaration	6	does that mean?
7	which was Miller 2, I guess, and and look at	7	A Seeing and treating patients with
8	your definition of I guess, which paragraph	8	triglyceride levels of at least 500 on a regular
9	would you say contains your definition of a person	9	basis, not once every five or ten years, but on a
10	of ordinary skill in the art.	10	relatively frequent basis.
11	A I believe we're looking at 15.	11	Q Okay. And going back to Exhibit 12
12	Q Okay. And where in 15 does it say that	12	which was that list of KOLs. Do you still have
13	a person of ordinary skill in the art is required	13	that?
14	to have treat VHTG?	14	A Yes.
15	A So, one, I never used the word	15	Q Thank you.
16	"required," and, secondly, Including severe	16	I think we left off the next one is
17	hypertriglyceridemia is the way that this the	17	Howard Weintraub?
18	two sentences are written, Including severe	18	A Yes.
19	hypertriglyceridemia. And cardiologists, as a	19	Q And is he do you know who that is?
20	general rule, do not see those patients.	20	A Yes.
21	At the University of Maryland, for	21	Q And is he someone who is at least a
22	example, within my division, the	22	person of ordinary skill in the art?
23	echocardiographers, the interventionalists, the	23	A I believe he would be.
24	electrophysiologist refer they hear about a	24	Q And an expert?
25	patient with very high triglycerides, they send	25	A I believe he would be.
1			

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Page 76
                                                Page 74
                And, again, you don't know how this
                                                            1
                                                                     Q
                                                                           Do you recall this document --
 2
    list was compiled; correct?
                                                                referring this document?
 3
                That is correct.
                                                                     Α
                                                                           I -- I really don't.
 4
                MR. CLEMENT: Can we take a break.
                                                                     0
                                                                           Can you take a second to just review
 5
                MR. KENNEDY: Yeah, it's a good time
                                                                it?
     for a break.
                                                                           (Witness reviews document.) Yes.
                                                                     Α
 7
                THE VIDEOGRAPHER: The time is
                                                            7
                                                                     Q
                                                                           Okay. Did reading it refresh your
     9:28 a.m. This completes tape number 1. We are
                                                                recollection as to what it's about?
 8
9
     going off the record.
                                                            9
                                                                           Yes.
10
                (Recess -- 9:28 a.m.)
                                                           10
                                                                           Okay. What -- what do you recall about
                (After recess -- 9:49 a.m.)
                                                                it?
11
                (Jennifer Scarpati and Deepti Jain
                                                           12
                                                                           Yeah. There was a -- there was a
12
                                                                primary care conference with Pri-Med. So this is
13
    present.)
                                                           13
14
                THE VIDEOGRAPHER: The time is 9:49
                                                                a conference that primary care physicians attend.
    a.m. This begins media unit number 2.
                                                                It's continuing medical education. And a
15
16
                Please proceed, Counsel.
                                                           16
                                                                colleague and I gave a talk related to hyp- -- I
          BY MR. CLEMENT:
                                                                spoke on hyp- -- just the general aspect of
17
                                                           17
18
                Dr. Miller, do you still have Exhibit
                                                                hypertriglyceridemia, and I believe he talked
19
     12 front of you?
                                                                about treatment.
20
          Α
                                                           2.0
                                                                           And I think that's probably where this
21
          Ω
                Just one further question. Bill
                                                           21
                                                                came from.
    Stirtan, do you know who that is? Did we talk
                                                           22
                                                                     0
                                                                           And who was the other colleague?
22
23
    about him before?
                                                           23
                                                                     Α
                                                                           I don't recall now.
                We may have. I think I remember
24
          Α
                                                           24
                                                                     Ω
                                                                           Okay. And was this part of your
    meeting him, but I don't know his whereabouts now.
                                                                consultancyship with Amarin --
25
                                                           25
                                                Page 75
                                                                                                           Page 77
    I don't believe he's with the company, but I just
                                                                     Α
                                                                           No.
    don't know.
                                                                           -- that you appeared at this?
3
                Okay. Do you know if he's -- do you
                                                                           No, so primary care -- I mean, Pri-Med
     understand -- does he practice medicine or --
                                                                conferences are CME conferences that are borne out
 5
                I don't think so, but, again, I don't
                                                                from Harvard.
 6
    know.
                                                                           And, so, one of my colleagues, Peter
 7
          Q
                                                                Libby, over at Harvard does the cardiology and
                Okay.
8
                MR. CLEMENT: All right. Let's mark
                                                                there are a number of colleagues from Harvard that
     the next document, document with Bates
                                                                are involved, so I get involved to speak at those.
9
                                                            9
    number 2702696.
                                                           10
                                                                           Do you know who Steven Ketchum is who
10
                (Miller Deposition Exhibit 13 was
                                                                wrote this email to you?
11
                                                           11
12
    marked for identification and attached to the
                                                           12
                                                                     Α
                                                                           I do.
13
    transcript.)
                                                           13
                                                                     0
                                                                           Okay. Who is Steven Ketchum?
          BY MR. CLEMENT:
14
                                                                           At the time at least of what was dated
15
                Dr. Miller, the court reporter has
                                                           15
                                                                May of 2013, he was president of research and
    placed before you what's been marked as Miller
                                                                development and senior vice president of Amarin.
16
                                                           16
17
    Exhibit 13. Have you ever seen this document
                                                           17
                                                                     0
                                                                           Okay. He sent you this little news
18
    before?
                                                                wire, right, at the bottom?
                                                           18
19
          Α
                I -- I don't recall, but I'm seeing it
                                                           19
                                                                     Α
                                                                           Correct.
20
                                                                           And you were a member of the -- well,
    now.
                                                           2.0
21
                Well, it's a email from Steven Ketchum
                                                                it says -- it says here that the firm says one
          Ω
                                                           21
    to you; correct?
                                                                lecture conducted by a member of Amarin's steering
22
                                                           22
23
          Α
                Yes.
                                                           23
                                                                committee.
                And dated May 28th, 2013?
24
          Q
                                                           24
                                                                           Are they referring to you there?
25
          Δ
                That's what it says.
                                                           25
                                                                     Α
                                                                           I don't believe so.
```

	02/13		
	Page 78		Page 80
1	Q Do you have any idea who they were	1	may have asked this before. Was Paresh Soni
2	referring to?	2	someone you considered a person of ordinary skill
3	A I believe it was probably the other	3	in the art?
4	speaker.	4	A Well, again, I don't know the extent to
5	Q Okay. And you still you don't	5	which he is still in the field. This was 2012, so
6	recall	6	at that time he was at the very least he was
7	A No.	7	familiar with the compound. And whether or not he
8	Q who that was?	8	had access to a clinician if he, himself, wasn't
9	Okay. And it says here that he said	9	seeing those patients, is another issue.
10	and, I guess, that's the other speaker? A Correct. It was a male.	11	Q So I guess I'm asking whether or not you can based on the knowledge as you sit here
12		12	today, you can't tell me you don't know whether
13	Q Male, okay. However fish oil is one of many	13	he was a person of ordinary skill in the art; is
14	treatments that can lower triglycerides; right?	14	that correct?
15	A That's what it says.	15	A Well, I think based upon so if I may
16	Q Okay. So there are other medications	16	and go back to my declaration.
17	that can lower triglycerides in addition to fish	17	MR. KENNEDY: Yeah, you might have I
18	oil; right?	18	think it's
19	A Correct.	19	THE WITNESS: And I will go to that
20	Q And do you know what that was for	20	section of person of ordinary skill in the art.
21	that was for levels above 500; right?	21	And I said, It is my opinion that a
22	A I I don't recall, so I'm like	22	POSA at the time of the invention would be a
23	you, I am looking at this at this text to	23	clinician with an M.D. or D.O so he qualifies
24	understand the context of it.	24	in that regard and at least two or three years
25	Q Okay. Do you recall having I mean,	25	experience of the diagnosis and diagnosis of
	Page 79		Page 81
1	it says here that, you know, in the top, the email	1	treatment of lip of treatment of lipid
2	portion, it talks about Mike is he's writing to	2	disorders including hypertriglyceridemia.
3	you, and he's saying he has some questions	3	So that's just the part I'm just unclear of.
4	regarding the newswire piece and for you to feel free to call him.	5	BY MR. CLEMENT:
5	Do you recall having a conversation	6	Q All right. So sitting here today, I
7	with him about this?	7	quess, in answer to my question, you don't you
8	A I I don't.	8	can't tell me whether or not he was a person of
9	Q Okay. Have you ever talked to the	9	ordinary skill in the art; right?
10	patent inventors in this case?	10	A At that particular time, back back
11	A Well, I think as I as I said, I	11	in 2011, that based on my that that
12	two of the patent inventors, Paresh Soni and Rene	12	again, this is my opinion, and it doesn't
13	Braeckman, who approached me during the early part	13	invalidate in any way the opinions offered in
14	of the trial, but they both left the company, and	14	number 17; otherwise, it wouldn't change my
15	I have not seen or spoken with them since.	15	opinions expressed in this declaration, provided
16	Q Since do you remember give me a	16	that the POSA as defined by defendants and
17	time frame?	17	plaintiffs is or has access to a clinician.
18	A I'm guessing they left the company	18	That's number 18.
19	around 2013, maybe, '12.	19	Q Okay. And right. This and if we
20	Q Okay.	20	look at paragraph 17, right, plaintiffs in their
21	A Somewhere between '12 and '13.	21	preliminary validity contentions, you know, they
22	Q And what about any of the other	22	don't make they don't talk about this severe
23	inventors on the patent?	23	hypertriglyceridemia; correct?
24	A I don't believe I recognize them.	24	A They mention expertise in lipid
25	Q Do you know if any of them what I	25	metabolism.
1		1	

Page 82 Page 84 1 But they don't men- -- mention severe 1 And what's your position there? 2 hypertriglyceridemia; correct? Α I am a professor of cardiovascular 3 They don't say severe medicine, epidemiology and public health at the hypertriglyceridemia. school of medicine. 5 Okay. 5 Can you define "epidemiology"? But they talk about expertise in lipid Epidemiology is the study of -- of 7 metabolism which might fall under the umbrella of populations and assessing various entities which 8 a VHTG. might be disease or characteristics at least from 9 So it may or may not include it. I'm a cardiovascular standpoint. 10 not saying it excludes it. It may or may not 10 When you say "populations," you're include it; right? talking a number of people; right? 11 11 Correct. 12 Correct. 12 Okay. What's a D.O.? And in your practice, do you also see 13 13 0 14 Α That's a -- a doctor of osteopathic 14 patients? medicine. 15 15 Α Yes. 16 0 Okay. And you also say alternatively, 16 0 Okay. And are they only patients who 17 right, a POSA that can be a nurse practitioner, 17 have severe hypertriglyceridemia? 18 physicians assistant with the criteria you spell 18 Α 19 out? 19 How -- I guess, what percentage of your 0 20 Α Yes. patients have severe hypertriglyceridemia? 21 So they don't have to be a doctor? 21 Α So let's call it just VHTG. 22 They don't have to -- they don't have 22 0 Okav. 23 to have a medical degree or an osteopathic degree, 23 Α It will make -- it will make -- it will but they certainly need to have experience in make it much easier --24 24 25 treating patients with lipid blood disorders that 25 Q Thank you. Page 85 Page 83 include severe hypertriglyceridemia. -- defined as a triglyceride of at 1 2 Can they prescribe medications, nurse least 500 milligrams per deciliter. 3 practitioners? In the U.S. population that -- the I think it depends on the state and the prevalence is approximately one in 100 same holds true for physician assistants. individuals. In my practice, I probably see 5 6 Again, turning back to the inventors, somewhere -- prior to my declaration, about 20 a 7 Rene Braeckman, sitting here today, can you tell month. So 20 a month would be a relatively small 8 me whether or not he meets your definition of a percentage of the patients that I see in general. person of ordinary skill in the art? 9 Are you affiliated with any other 9 10 Again, based on this, I -- I don't medical institutions? 10 He may. 11 know. 12 Q All right. 12 And, I guess, what percentage of your 13 He may not. I don't know. time, a ballpark, in any given year do you spend 13 14 All right. Sitting here today, you 14 seeing patients? 15 don't know; correct? 15 Α I believe I have in my declaration Α That is correct. approximately two-thirds. 16 16 17 And you don't know any of the other 17 Q And do you prescribe medications? inventors, so you can't opine on whether or not 18 Α 18 19 they would meet that --19 0 Do you describe -- prescribe blood 20 Α That --20 thinners? 21 0 -- criteria? 21 Α I do. 22 -- is correct. Α 22 0 To patients with over -- who are VHTG? 23 Ω Okay. Now, you're affiliated with the 23 Α If they need it. 24 University of Maryland, Baltimore; is that right? So you do have patients who are over --24 0 25 who are VHTG and on blood thinners? Δ Yes

1				
		Page 86		Page 88
1	A	Yes.	1	Q And they usually have a date on them
2	Q	Do you prescribe Lovaza?	2	with the last revision?
3	A	Yes.	3	A I'll accept that.
4	Q	Vascepa?	4	Q Okay. And that would be the date of
5	A	It's Vascepa, yes.	5	the package insert?
6	Q	Vascepa, okay. Thank you. I've been	6	A I don't know, but I'll accept that.
7	pronounci	ng it wrong for a few years now.	7	Q Okay. All right. Turning back to the
8		And that's an Amarin product; right?	8	person of ordinary skill in the art, I think you
9	A	Yes.	9	stated in your declaration and feel free to
10	Q	Is that their only product?	10	look at it but that we you have in there a
11	A	I don't know.	11	2009 date for the person of ordinary skill in the
12	Q	Okay. Do you prescribe statins?	12	art, I think, if you look at paragraph 14.
13	A	Yes.	13	A Yes.
14	Q	Ezetimibe, if I pronounce that	14	Q And do you know how you came up with
15	correctly		15	that date?
16	A	Ezetimibe or Zetia.	16	A Yeah, I believe that was when the
17	Q	Ezetimibe or Zetia, yes.	17	earliest patent application was filed.
18	A	Yeah.	18	Q Give me one second here.
19	Q	Fenofibrates?	19	MR. CLEMENT: Sorry about that. Let's
20	A	Yes.	20	mark as Miller Exhibit 14 a copy of U.S. patent
21	Q	Do you prescribe fenofibrates to	21	number 8,293,728.
22	-	who are VHTG?	22	(Miller Deposition Exhibit 14 was
23	A	Yes.	23	marked for identification and attached to the
24	Q -	What about niacin?	24	transcript.)
25	A	I don't use a whole lot of niacin any	25	BY MR. CLEMENT:
		Page 87		Page 89
1	more.	Page 87	1	Page 89 Q Dr. Miller, the court reporter has
1 2	more.	Page 87 But you still do you still do		-
		But you still do you still do	1	Q Dr. Miller, the court reporter has
2	Q prescribe A	But you still do you still do it? There might be a patient who has been	1 2	Q Dr. Miller, the court reporter has marked put before you as Miller Exhibit 14 the
2 3 4 5	Q prescribe A on the me	But you still do you still do it? There might be a patient who has been dication for many years that does not	1 2 3 4 5	Q Dr. Miller, the court reporter has marked put before you as Miller Exhibit 14 the '728 patent. And you've reviewed that; right? A Yes.
2 3 4 5 6	Q prescribe A on the me want to g	But you still do you still do it? There might be a patient who has been dication for many years that does not o off of it, so but I do not it	1 2 3 4 5 6	Q Dr. Miller, the court reporter has marked put before you as Miller Exhibit 14 the '728 patent. And you've reviewed that; right? A Yes. Q And, I guess, do you know where on this
2 3 4 5	Q prescribe A on the me want to g would be	But you still do you still do it? There might be a patient who has been dication for many years that does not o off of it, so but I do not it uncommon for me to initiate a new script	1 2 3 4 5 6 7	Q Dr. Miller, the court reporter has marked put before you as Miller Exhibit 14 the '728 patent. And you've reviewed that; right? A Yes. Q And, I guess, do you know where on this patent it shows where the filing dates were for
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q prescribe A on the me want to g would be for niaci Q package i A Q labels so inserts? A Q in coordi	But you still do you still do it? There might be a patient who has been dication for many years that does not o off of it, so but I do not it uncommon for me to initiate a new script n. Okay. And are you familiar with nserts? Yes. Also do you also refer to them as metimes, or do you prefer package It doesn't matter. Okay. And do pharmaceutical companies nation with FDA often get revisions to kage inserts? MR. KENNEDY: Objection to form. Go go ahead.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Dr. Miller, the court reporter has marked put before you as Miller Exhibit 14 the '728 patent. And you've reviewed that; right? A Yes. Q And, I guess, do you know where on this patent it shows where the filing dates were for the by which you determine the 2009 date for a person of ordinary skill in the art? A Well, I'm not sure this patent refers to the 2009 there there was a '727 and other patents that preceded it. Q Okay. But if you look at if you look at the front page of this document, okay? A Yes. Q You see, like, in the left hand column there's numbers in parentheticals? A I see those numbers. Q Okay. And there's one that says 60? A Yes.
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02/15/2018 90 to 93 Page 90 Page 92 1 So the earliest -- if we want to get to a lipid disorder when it's not. 2 the actual date, the earliest date that this Well, let me ask you this question. 3 application has for its priority, at least on the Would you turn to paragraph 17 of your declaration front page of this document, is February 10, 2009; which has plaintiff's definition and their 5 right? validity -- preliminary validity contentions. 6 That's what it says. Uh-huh. 7 Okay. And I think we've already agreed 7 Q How many people have an advanced degree that paragraph 15 of your opening declaration, and advanced training expertise in lipid 8 9 that's where your definition of the person of 9 metabolism or cardiology or have experience in the 10 ordinary skill in the art is? diagnosis, evaluation and treatment of blood 11 disorders? How many of those do you think are in Okay. How many people in the United the Baltimore area? 12 States do you think meet your definition of the Probably about a dozen. 13 13 You realize this doesn't limit it to 14 person of ordinary skill in the art? Q I would say -- I don't have -- I can't people who treat VHTG? 15 15 16 give you a number. 16 Α So that -- that -- my interpretation here would include the treatment of VHTG -- would 17 Q How about a -- you're in the Baltimore 17 18 area? Is that where your practice is? include --19 (Witness nods head.) 19 Would include but wouldn't be limited 0 20 How many in the Baltimore area do you 20 to that; right? 21 think meet your definition of the person of 21 Α 22 ordinary skill in the art? 22 0 So if we don't limit it to people who 23 Oh, probably about one to two dozen. 23 treat VHTG, you think there's only a dozen people Α And do you know what the NLA is? in the Baltimore area that meet that definition? 24 Ω 24 25 Α 25 Probably, give or take. I do. Α Page 91 Page 93 1 And what is the NLA? Q Have you ever heard of the term NLA is the National Lipid Association "dyslipidemia"? 3 which is at -- the flagship organization for those Α Yes. interested in lipid disorders and treating lipid Q What does that mean? 5 disorders. Α Abnormal level of lipids and/or 6 What about in the D.C. area? Do you lipoproteins. 7 have an estimate of how many doctors you think in Q So is that only people who have VHTG? 8 the D.C. area or people in the D.C. area would Α be -- meet your definition of a person of ordinary 9 What about the term "monotherapy"? skill in the art? Have you ever heard that -- heard that term 10 I would have to look to see. I'm not before? 11 11 as familiar with --12 Α MT, yes. 13 0 Okay. 13 0 And what does that mean? 14 Α -- the -- who I might view as experts 14 Α Monotherapy, to me, is using a single 15 in this area. 15 druq. But how many cardiologists do you think What about the term "adjunct" or 16 0 16 17 there are in the Baltimore area? 17 "adjunctive therapy"? 18 Myself and at least three at Johns 18 Α Very general term. Α 19 Hopkins. 19 0 Okay. What does that term mean? 20 Are the only cardiologists? 20 Α Adding to -- adding therapy to whatever Ω 21 Α That are interested in lipids. 21 is existing already. 22 0 Okay. What about --22 So you have -- if you have adjunctive Q 23 But -- that treat lipid disorders --23 therapy, the therapies are overlapping?

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Α

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It could be.

They're happening at the same time?

not treating a patient that comes in -- that they

put on a statin for an elevated LDL that they call

24

Page 94 Page 96 1 Α Patients can take -- can incorporate 1 I quess, what is your understanding of 2 them together. what claim construction is? 3 Q They're concomitant? 3 Α If I may refer back to my declaration --4 Well, concomitant, the way it's defined 5 in this specific patent refers to lipid-lowering Q Uh-huh. therapy, so that's outside the definition that Α -- where I define "claim construction 7 you're referring to. But within the scope of this principles," and that's on page 7. And that is a patent, concomitant refers to lipid-lowering claim term that is given its plain and ordinary 8 9 medication -- medications. meaning as it would be understood by a person of 10 Okay. But at -- at -- what I'm asking the ordinary skill in the art within the context you is, adjunctive therapy, is that similar to of patent claims, specification, prosecution 11 concurrent therapy? history. 12 13 MR. KENNEDY: Objection to form. 13 0 Anything else? 14 THE WITNESS: It may or may not be. It could be extrinsic evidence as well. Okay. Have you ever heard of the 15 BY MR. CLEMENT: 15 16 Is it similar to concomitant therapy? 16 doctrine of claim differentiation? 17 MR. KENNEDY: Same objection. 17 18 THE WITNESS: It may or may not be. 18 0 And you cite to the prosecution history 19 BY MR. CLEMENT: 19 in support of what a claim construction could be; 20 How -- how might it not be? 20 right? 21 Well, so the way I view concomitant 21 Α Yes. 22 therapy, for example, in the sense of taking a 22 0 What is your understanding of what a 23 combination of lipid-lowering medications would be 23 prosecution history is? that a patient has -- is -- comes in, is found to 24 24 Well, prosecution history is basically 25 have hyperlipidemia and is placed on a statin. all of the elements -- the history behind the --Page 95 Page 97 LDL is still high so that ezetimibe is added to the patent submission. continue LDL reduction. And have you ever been involved in a So that is -- I would view that as 3 patent prosecution proceeding? concomitant lipid-lowering therapy. Α 5 Would you view that as adjunctive And before this case, have you ever Q 6 therapy? looked at a prosecution history? 7 Α I don't think of it like that. I just I don't believe so. 8 don't. Now, in paragraph 20 of your report, 9 But adjunctive therapy is still you talk about the patentee can expressly define 9 overlap -- therapies that overlap? the claim term. 10 Therapies that overlap, but in the 11 11 Do you see that? field we -- I don't think of it like that. 12 12 Α 13 Do you own -- have any -- are you an 13 0 Did you find any express definitions on 0 14 inventor on any patents? the claim terms you opined on? 14 15 Α Not as of 2009. 15 Α If I may go through. 0 How about to- -- as you sit here today? 0 Sure. Take a minute. 16 16 17 Not today. 17 Α (Witness reviews document.) 18 0 Are you an inventor on a patent 18 So if we go to . . . 19 application? 19 (Witness continues reviewing document.) Α Not today. 20 Yes, I think throughout where there's 2.0 21 Not today, okay. 21 discussion as to the use of this medication to It's like -- what I'm trying to get at lower triglycerides without raising LDL and/or to 22 22 23 is, you know, your prior experience with patents, 23 lower ApoB which is certainly within the -let's say, in 2009 -- well, let's -- let's say --24 24 something that I've spoken about. 25 well, strike that. 25 Okay. I'm asking do you have any

Page 98 Page 100 instances of where the patent specification gave 1 BY MR. CLEMENT: 2 you an express -- an express definition of a claim And that's -- you have the '728 patent, 3 column -- you rely on the columns 12, lines 43 to 46 for that? 4 I guess -- I'm confused by your answer. 5 Maybe you can help make --Α (Witness reviews document.) 6 I guess --And you consider that as the declarant 7 MR. KENNEDY: Objection to form. of your deposition, you consider that to be -- I 8 THE WITNESS: I guess, I'm confused by just want to get your testimony correct. 9 your question. 9 You -- as the declarant of this 10 BY MR. CLEMENT: 10 declaration, you consider that to be an express You say here in paragraph 20, right, I definition that the patent was given; correct? 11 also -- I also understand that the patentee may 12 MR. KENNEDY: Objection to form. 12 expressly define the claim term in the patent THE WITNESS: I think this is one of a 13 13 14 specification, and if the claim is defined, then number of examples as it relates specifically to 15 that definition will govern. 15 the specification. 16 So I guess I'm asking you was there a 16 BY MR. CLEMENT: 17 place in the patent that you looked to -- the 17 That's not what I'm asking. 18 patent specification that you looked to that gave 18 I'm asking as the declarant, the person 19 an express definition of a claim term. And you 19 whose opinions are contained in your declaration, 20 said, okay, that's what the specification said; 20 you consider what is at column 12, lines 43 to 46, 21 that's how it's defined? 21 to be an express definition; is that correct? 22 Yeah, I think for -- in the instance of 22 MR. KENNEDY: Objection to form; asked 23 administering, for example, that's one example in 23 and answered. the patent specification -- I mean, in the THE WITNESS: Yeah, I -- as I've 24 24 25 prosecution history. already said, I'm not an attorney and based on the Page 99 Page 101 1 I'm asking the patent specification. information as presented with -- with regard to Α I believe there are in the patent the specification on concurrent lipid-altering 3 application and patent specification. There are therapy and concomitant lipid-altering therapy in instances where I've discussed that, so I'm going one embodiment within the '728 claim -- the '728 to have to go through these. So if you give me a patent, that that information suggests that. 5 6 moment here. BY MR. CLEMENT: 7 If we go to page 24, under number 55, Well, that's one embodiment; right. An 8 in discussing lipid-altering therapy, it is clear embodiment is an example. It's not a definition; from the specification that concurrent and right? 9 9 concomitant lipid-altering therapy concur solely 10 MR. KENNEDY: Objection to form. 10 THE WITNESS: 11 to medications. For example, the specification 11 Correct. describes that in one embodiment the subject being BY MR. CLEMENT: 12 12 13 treated in accordance with methods of the 13 Okay. So is that an expressed 0 14 invention is not otherwise on lipid-lowering definition -- sitting here today -- you're the one 15 therapy. For example, statin, fibrate, niacin 15 who wrote the declaration and offered opinions and you talked about expressed definitions in your 16 and/or ezetimibe therapy. 16 17 And you consider that an express 17 declaration. I'm just asking you is that -- under 18 definition; is that your testimony? your understanding, not an attorney's -- under 18 your understanding as a declarant offering 19 MR. KENNEDY: Objection to form. 19 20 THE WITNESS: Well, I'm not an opinions in this case if what's at columns 12,

lines 43 to 46, is an expressed definition of the

MR. KENNEDY: Same objection.

THE WITNESS: Yeah, and I think you

term "concurrent or concomitant lipid-altering

21

22

23

24

25

therapy"?

21

22

23

24

25

attorney, but based on what is written, I go into

a claim term within the patent specification, and

lipid-altering therapy to the extent that is

that claim term here relates to concurrent

discussed in the specification.

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Page 102
                                                                                                           Page 104
 1
    need to review not only the term and the
                                                            1
                                                                           MR. KENNEDY: Objection to form.
 2
     specification, but you also need to review the --
                                                            2
                                                                           THE WITNESS: Yes, I -- I have not
 3
     and incorporate prosecution history and extrinsic
                                                                relied uniquely on the patent specification. I've
     evidence.
                                                                considered it as I've considered all of the
 4
 5
          BY MR. CLEMENT:
                                                            5
                                                                intrinsic evidence and to some extent extrinsic
 6
                If it was an expressed definition,
                                                                evidence. So I've looked at all the information
 7
     would you need to consult the prosecution history
                                                                presented to me.
 8
     as well?
                                                            8
                                                                     BY MR. CLEMENT:
 9
                MR. KENNEDY: Objection to form.
                                                            9
                                                                           Understood.
10
                THE WITNESS: And, again, I'm not an
                                                           10
                                                                           I'm asking a question. You know,
     attorney, so I'm -- I'm not as -- as --
                                                                it's -- to me, it's a yes/no question, but -- are
11
          BY MR. CLEMENT:
                                                                there any instances where you thought that in the
12
                                                                specification there was an express definition of a
13
                When you say --
                                                           13
14
                -- as well as an expert in
                                                                patent claim term that you opined on?
     this specific --
15
                                                           15
                                                                           MR. KENNEDY: Objection to form.
16
          0
                In paragraph 20 you say -- I
                                                           16
                                                                           THE WITNESS: Yeah, I'm not sure that I
                                                                did.
17
    understand, right, that the patentee may expressly
                                                           17
18
    define the claim term in the patent specification,
                                                           18
                                                                     BY MR. CLEMENT:
19
     and if the term is defined, then that definition
                                                           19
                                                                     0
                                                                           Okay. Now, the next part of your
20
    will govern.
                                                           20
                                                                sentence -- your statement in paragraph 20 talks
                                                                about the prosecution history, right, where there
21
                So there will be no need to go to the
                                                           21
22
    prosecution history, right, if there was an
                                                           22
                                                                can be an intentional disavowal or a limiting of
23
    express definition?
                                                           23
                                                                the scope of the claim; right?
                Well, but the next sentence says, I
24
                                                           24
                                                                     Α
                                                                           Yes.
25
    understand that an applicant may also
                                                           25
                                                                     0
                                                                           Did you find instances of either of
                                               Page 103
                                                                                                           Page 105
     intentionally disavow or limit the scope and claim
                                                                those, an intentional disavowal -- I quess, strike
     of the statements made to the patent office during
                                                                that. Let's take it back a step.
 3
    prosecution which is prosecution history.
                                                            3
                                                                           What do you mean by "intentionally
 4
                Understood.
                                                                disavow"?
                But, again, if the term is defined and
                                                            5
                                                                     Α
                                                                           Oh, boy. Go against, disprove.
 5
 6
     that definition -- are you telling me that what's
                                                                           Okay. But intentionally disavow or
 7
     at column 12, lines 43 to 46 -- is that or is that
                                                                limit the scope of a claim -- so I guess take it
8
     not an express definition of the claim term
                                                                in context.
     "concurrent or concomitant lipid-altering
                                                            9
                                                                     Α
9
     therapy"?
                                                                           Are you still good with go against or
10
                                                           10
                                                                     Q
11
                MR. KENNEDY: Objection to form.
                                                           11
                                                                disprove?
12
                THE WITNESS: Yeah, I'm not sure. In
                                                           12
                                                                     Α
                                                                           Yeah, that's fine.
13
     and of itself, it's an expressed term, but it is
                                                           13
                                                                     0
                                                                           Okay. What about limit? Same?
14
     certainly one example of -- as noted in the
                                                           14
                                                                     Α
                                                                           Yeah.
15
     specification for which concomitant/concurrent --
                                                           15
                                                                     0
                                                                           And are there any instances of an
          BY MR. CLEMENT:
                                                                intentional disavowment or limitation of the scope
16
                                                           16
17
                Okay.
                                                           17
                                                                of a claim in a statement made to the patent --
18
          Α
                -- therapies --
                                                                patent office during prosecution that you relied
                                                           18
19
          0
                So you're not sure. That's fine.
                                                           19
                                                                on in your declaration?
20
    That's a fair answer.
                                                           20
                                                                     Α
                                                                           I don't believe so.
21
                I'm asking you are there any instances
                                                           21
                                                                           Now in paragraph 21 you discuss the use
                                                                     0
     in the patent specification where you think the
                                                                of extrinsic evidence; right?
22
                                                           22
23
    patentee expressly defined a claim term in the
                                                           23
                                                                     Α
                                                                           That is correct.
24
                                                                           What is extrinsic evidence?
    patent specification that you have relied on in
                                                           24
                                                                     Q
25
    your declaration?
                                                           25
                                                                     Α
                                                                           Well, it is information that may have
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to 105

	02/15	, , C	106 to 109
1	Page 106 not been part of the original submission related	1	Page 108
2	to the patent prosecution history specification.	2	Q Do you know if extrinsic evidence is
3	Q Do you know what intrinsic evidence is	3	given lesser or greater import than intrinsic
4	with regard to claim construction proceeding?	4	evidence?
5	A Intrinsic evidence incorporates.	5	MR. KENNEDY: Objection to form.
6	Q The intrinsic?	6	THE WITNESS: I would say it's given
7	A Extrinsic evidence is is outside of	7	less evidence.
8	the intrinsic evidence.	8	BY MR. CLEMENT:
9	Q Okay. And what is the intrinsic	9	Q When did you first learn of using fish
10	evidence?	10	oil in treating lipid blood disorders?
11	A And the intrinsic evidence includes	11	A Well, my interest in fish oil dates
12	specification, prosecution history.	12	back to 1987. I was a Fellow at Johns Hopkins
13	Q And the claims?	13	and actually it dates earlier than that. To
14	A And the claims.	14	get the position at Hopkins I had to write a
15	Q Okay. And extrinsic evidence is	15	grant.
16	anything other than the intrinsic evidence; right?	16	So it was an NIH grant that looked at
17	A Yes.	17	the how different fatty acids were taken up,
18	Q Okay. Are you aware of any limitations	18	and it was my idea for the grant submitted the
19	on the use of extrinsic evidence in claim	19	grant. It was funded. We did the study. And it
20	construction?	20	was the first demonstration of looking at
21	MR. KENNEDY: Objection to form.	21	different oils taken up by cellular into the
22	THE WITNESS: Again, I'm not an	22	cells of a fibroblast.
23	attorney, and I don't know.	23	And I looked at palmitate, oleate. So
24	BY MR. CLEMENT:	24	palmitate is a saturated fat. Oleate is an
25	Q Yeah, I'm not asking as an attorney.	25	example of a monounsaturated fat. And I also
	Page 107		Page 109
1	I'm asking as a declarant.	1	looked at EPA. Back in those days EPA was quite
2	You relied on some extrinsic evidence;	2	expensive. I used half my grant to buy EPA, but
3	right?	3	there had been no data in the field at that time.
4	A I did.	4	And showed it was one of those ah-ha
5	Q Okay. I'm just wondering are you	5	moments when I looked at the simulation counter
6	aware of any limitations on the use of extrinsic	6	and found that when you use EPA compared to
7	evidence in claim construction?	7	palmitate or oleate, it was directly taken up into
8	A Well	8	cellular phospholipids with minimal amount taken
9	MR. KENNEDY: Objection to form.	9	up into triacylglycerol.
10	THE WITNESS: Only insofar as if the	10	And, so, that sparked interest in in
11	extrinsic evidence comes out after the patent	11	understanding this field better. So this was
12	application has been submitted.	12	back this was circa circa 1987 when I did
13	BY MR. CLEMENT:	13	those experiments.
14	Q So if it postdates that 2009 date A Yes.	15	So that was my first entry into the field and subsequent to that the studies came out
16	Q it shouldn't be considered; right?	16	to show that actually a triglycerides are
17	A Well, the 2009 I think we have	17	reduced in patients that had degrees of
18	patents that extend into the 2012, 2013 time	18	hypertriglyceridemia, and, so, there are studies
19	frame. I mean, there are a number of different	19	done here in the States as well as outside the
20	patents.	20	U.S. that have demonstrated in
21	Q Right. But they all rely on a 2009	21	hypertriglyceridemic states omega-3
22	filing date; right?	22	was preference. I mean, we actually identified
23	A Right. Correct. Correct.	23	the mechanism by which we believe to be taken
24	Q So anything after that 2009 date should	24	up at the cell level.
	not be considered extrinsic evidence; right?	25	And studies have demonstrated time and
25	HOU DE CONSTRETER EXCELHISIC EVIRENCE, LIGHT:		

		1	
1	Page 110 again that omega-3 preps, EPA, DHA as well, can	1	Page 112 BY MR. CLEMENT:
2	reduce can lower triglycerides pretty	2	Q The Epadel, okay.
3	significantly.	3	Just so far as you know, it wasn't used
4	Q Now, EPA, that's icosapent?	4	to treat VHTG?
5	A Correct.	5	A Yeah, I'm not I don't recall
6	Q And in that grant that you were talking	6	publications on VHTG.
7	about that you did back in circa 1987, were you	7	Q Okay. But you do recall hearing about
8	getting purified EPA?	8	Epadel before 2009?
9	A Got purified EPA.	9	A Yes.
10	Q Do you recall how pure?	10	Q To try high triglycerides at least?
11	A It was as far as I knew, it was over	11	A No, it was not used to treat high
12	95 percent pure.	12	triglycerides.
13	Q Now, when was the first time you	13	Q What was it used to treat?
14	learned of using purified EPA to treat high or	14	A It was it was used in a clinical
15	VHTG?	15	trial called JELIS, and there was an outcome
16	MR. KENNEDY: Objection to form.	16	study. And, in fact, I believe they excluded
17	THE WITNESS: Well, in in in the	17	patients that had VHTG. So it was specifically
18	United States, we I don't recall that we had a	18	looking at whether or not the addition of this
19	purified EPA product that was available until	19	compound to standard of care in a Japanese
20	Vascepa came out.	20	population would lower their risk of
21	BY MR. CLEMENT:	21	cardiovascular events. It was a non-VHTG
22	Q What about not in the United States?	22	population.
23	A Yeah. There were preparations that	23	Q Okay. Even though it was a non-VHTG
24	were not used in the United States.	24	population, was it used to treat lowering
25	Q What preparation were those?	25	triglycerides in this non-VHTG population?
	D 111		
1	Page 111 A There was a a preparation that was	1	Page 113 MR. KENNEDY: Objection to form.
1 2	5	1 2	
	A There was a a preparation that was		MR. KENNEDY: Objection to form.
2	A There was a a preparation that was also EPA based.	2	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not.
2 3	A There was a a preparation that was also EPA based. Q Can you tell me what it was?	2 3	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT:
2 3 4	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation	2 3 4	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for?
2 3 4 5	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed.	2 3 4 5	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had
2 3 4 5 6	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG?	2 3 4 5 6	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the
2 3 4 5 6 7	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form;	2 3 4 5 6 7	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride
2 3 4 5 6 7 8	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of	2 3 4 5 6 7 8	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was
2 3 4 5 6 7 8	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it	2 3 4 5 6 7 8	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the
2 3 4 5 6 7 8 9	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it MR. KENNEDY: the	2 3 4 5 6 7 8 9	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the studies that have for example, the MARINE study
2 3 4 5 6 7 8 9 10	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it MR. KENNEDY: the THE WITNESS: was	2 3 4 5 6 7 8 9 10	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the studies that have for example, the MARINE study that had come out in VHTG patients.
2 3 4 5 6 7 8 9 10 11	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it MR. KENNEDY: the THE WITNESS: was MR. KENNEDY: declarations.	2 3 4 5 6 7 8 9 10 11 12	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the studies that have for example, the MARINE study that had come out in VHTG patients. Q So in the JELIS study or the use of
2 3 4 5 6 7 8 9 10 11 12	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it MR. KENNEDY: the THE WITNESS: was MR. KENNEDY: declarations. THE WITNESS: As far as I know, it was	2 3 4 5 6 7 8 9 10 11 12 13	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the studies that have for example, the MARINE study that had come out in VHTG patients. Q So in the JELIS study or the use of Epadel, they weren't measuring reductions in
2 3 4 5 6 7 8 9 10 11 12 13 14	A There was a a preparation that was also EPA based. Q Can you tell me what it was? A Well, it was Japanese. A preparation known as Epadel was marketed. Q That was to treat VHTG? MR. KENNEDY: Objection to form; outside the scope of THE WITNESS: Yeah, it MR. KENNEDY: the THE WITNESS: was MR. KENNEDY: declarations. THE WITNESS: As far as I know, it was not used to treat VHTG. The first time that my	2 3 4 5 6 7 8 9 10 11 12 13	MR. KENNEDY: Objection to form. THE WITNESS: No, it was not. BY MR. CLEMENT: Q What was it used for? A It was used to determine whether it had cardioprotective effects. And, in fact, in the original study, the amount of triglyceride reduction was was about 5 percent. It was not nowhere near as robust as we see with the studies that have for example, the MARINE study that had come out in VHTG patients. Q So in the JELIS study or the use of Epadel, they weren't measuring reductions in triglycerides in the patient population that was
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	02/15)/2()18 114 to 117
	Page 114		Page 116
1	measure in that JELIS study?	1	triglyceride levels with this particular therapy
2	MR. KENNEDY: Objection to form.	2	was really the the first demonstration of
3	THE WITNESS: It was one of a number of	3	effectiveness without causing undue related
4	many, many markers, so I would discount the	4	issues.
5	relevancy of triglyceride in this study.	5	Now, I do talk about the effects on LDL
6	BY MR. CLEMENT:	6	and ApoB a little bit later on
7	Q Okay. Now, in paragraph 22 of your	7	Q Right.
8	declaration, you talk about how or determine	8	A but, no, for this particular
9	what the patents were related to; right?	9	paragraph, that's the way this paragraph was
10	Do you see that?	10	written.
11	A I do.	11	Q Okay. And did it come from the claims
12	Q How did you determine what to put in	12	of the patent? And I agree you have other stuff
13	that statement?	13	in here, but I'm just asking whether or not this
14	A Well, that that was that was	14	paragraph did it come from the claims?
15	determined based on the dose used in the MARINE	15	A I'd have to go look at all the claims
16	trial to cause reductions in triglyceride as well	16	to see if I took word for word out of this, but I
17	as not to raise levels of LDL, also lowered levels	17	think this is just a general idea of of the
18	of ApoB.	18	reason for considering this particular medication.
19	Q It says nothing about LDL or ApoB in	19	Q Did the claims play a role in forming
20	paragraph 22; right? I'm not missing something?	20	your opinion in paragraph 22?
21	A That's correct, not in that particular	21	MR. KENNEDY: Objection to form.
22	paragraph.	22	THE WITNESS: Well, the claims talk
23	Q Did you look at the claims of the	23	about some elements noted in paragraph 22.
24	patents-in-suit because you I mean strike	24	BY MR. CLEMENT:
25	that.	25	Q Okay. Which elements?
	Page 115		Page 117
1	Did you look at the claims of the	1	A Very high very high triglyceride
2	patents-in-suit in figuring out what to say in	2	levels. Now, the claims might say 500 to 1500.
3	paragraph 22?	3	They generally talk about the dose of 4 grams, and
4	MR. KENNEDY: Objection to form.	4	they and some of the claims talk about some of
5	THE WITNESS: I looked at the	5	the well, some of those effects are also
6	patents-in-suit, but the patents really relate to	6	are are discussed in in the prosecution
7	the use of this compound ethyl icosapent at a dose	7	history. Some of them so if this is kind of a
8	of 4 grams a day in patients with very high	8	statement related to
9	triglycerides.	9	Q But some of them are talked right,
10	BY MR. CLEMENT:	10	the cause-specific effects on lipid parameters in
11	Q So you didn't look at the claims in	11	patients; right? Some of those are talked about
12	coming to this statement; is that your testimony?	12	in the claims; right?
13	MR. KENNEDY: Objection to form.	13	A If I may refer to '728
14	THE WITNESS: I looked at the claims	14	Q Sure.
15	for this study.	15	A So if we look at '728 in claim 1, it
16	BY MR. CLEMENT:	16	does say it's a method of reducing triglycerides
17	Q You looked at the claims of the	17	in a VHTG patient and goes on to say to effect a
18	patent	18	reduction in triglycerides without increasing LDL.
19	A Of the patents, correct.	19	Q So that's part of so part of
20	Q in coming to this statement in	20	paragraph so just correct me if I'm wrong. You
21	paragraph 22?	21	did consider the claims in coming to your
22	A Well, I think this is just one	22	statement in paragraph 22 of your declaration;
23	paragraph. As we go on, we talk more about some	23	right?
24	of the other elements. But as far as technical	24	A Yes.
25	background, the idea of treating very high	25	Q And here you say, To cause specific

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		Page 118		Page 1
1	effects or	n the lipid parameters in patients;	1	paragraph 22 that there's a method of treating;
2	right? Is	s that correct?	2	right? What is your definition of "treating"?
3	A	To cause specific effects.	3	A Well, in this particular case it's
4		Well, we know now; it was not	4	using the medication ethyl icosapent
5	appreciate	ed back then. So when the study was	5	Q To relieve the symptoms or to relieve
6	designed,	the finding of a a rise or lack of a	6	the VHTG?
7	rise in LI	OL was unexpected finding.	7	A To lower triglycerides and perhaps
8	Q	Understood.	8	other effects.
9	A	But at the time when I wrote this,	9	Q Now, if you look at the '728 patent for
10	it was		10	me at column 2, line 33 to 40.
11	Q	And you said it it was to cause the	11	Do you see that section?
12	specific 6	effects on lipid parameters in patients;	12	A I do.
13	right?		13	Q If you'll just read that to yourself
14	A	Correct.	14	and let I guess, my question while you're
15	Q	In paragraph 22?	15	reading that is if that's basically your
16	A	Correct.	16	understanding of what treatment means with regard
17	Q	You did not say intend to cause;	17	to these patents.
18	correct?		18	A (Witness reviews document.)
19		MR. KENNEDY: Objection to form.	19	Yes, I'll agree with that.
20	BY M	R. CLEMENT:	20	Q Okay. And you also discuss ApoB in
21	Q	Correct?	21	your report?
22	A	Correct.	22	A I do.
23	Q	Okay. And what is your definition of	23	Q Okay. ApoB is short for what
24	"patients'	1?	24	apolipoprotein B?
25	A	Well, as it relates to the to the	25	A Apolipoprotein B.
1	natonta ir	Page 119	1	Page 1
2		this particular case, patients are a a class of individuals who have very	2	·
3		Lyceride defined as a	3	
4	Q		~	
5	×	OKAV.	4	
	Α	Okay.	4 5	Q We'll just use ApoB.
	A O	triglyceride of at least 500.	5	Q We'll just use ApoB. A Sure.
6	A Q	triglyceride of at least 500. Very good. That that's fine.	5	Q We'll just use ApoB. A Sure. Q What is ApoB?
6 7	Q	triglyceride of at least 500. Very good. That that's fine. I guess, what is a patient in	5 6 7	Q We'll just use ApoB. A Sure. Q What is ApoB? A Well, it is a it is a protein that
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6 7 8 9	Q general	triglyceride of at least 500. Very good. That that's fine. I guess, what is a patient in I guess, can you give me your general of "patient"?	5 6 7 8 9	Q We'll just use ApoB. A Sure. Q What is ApoB? A Well, it is a it is a protein that resides on the surface of lipoprotein particles. There are lot of different ApoBs and lots of
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	general definition you're ref BY ME Q A one or mon for evalua Q a patient A Q back to th	triglyceride of at least 500. Very good. That that's fine. I guess, what is a patient in I guess, can you give me your general of "patient"? MR. KENNEDY: Objection to form. THE WITNESS: Yes. So this is Terring to something outside R. CLEMENT: Outside the patent. outside the patent. A patient is someone who has various The medical issues that they're coming in ation. And would you agree a individual can be or may not be a patient; right? I would agree. Okay. And when we go back going	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q We'll just use ApoB. A Sure. Q What is ApoB? A Well, it is a it is a protein that resides on the surface of lipoprotein particles. There are lot of different ApoBs and lots of different Apo- lipoproteins. And they may be taken up by specific receptors or send signals to allow that particle to be metabolized and so forth. Q And is it used as a measure of the number of VLDL, IDL, and LDL particles in the blood? A Yes, it's it is often used as a surrogate for the so-called non-HDL so all lipoproteins but HDL. Q And who uses it as such a measure? A Well, oftentimes it's it's used in clinical trials. Q How about in general practice? A Not commonly.

	02/13		122 00 125
	Page 122		Page 124
1	order when you take blood and do you order	1	A Uh-huh. I do.
2	an ApoB	2	Q Downloaded on November 13, 2014.
3	A Not	3	Do you see that?
4	Q level?	4	A I do.
5	A Not usually. I might on some	5	Q Did you download it on November 13,
6	occasions, but not all the time.	6	2014?
7	Q Let's mark the next exhibit we're up	7	A I don't recall.
8	to	8	Q Did this document come from counsel for
9	THE COURT REPORTER: Fifteen.	9	preparation of your report?
10	MR. CLEMENT: 15 a document with	10	A It could have. I've certainly have
11	a Bates range 289915 through 290194.	11	downloaded the report in the past. I just don't
12	(Miller Deposition Exhibit 15 was	12	know if that was the day I did it.
13	marked for identification and attached to the	13	Q So if you turn to page 289557
14	transcript.)	14	MR. KENNEDY: I'm sorry. Did you say
15	BY MR. CLEMENT:	15	557?
16	Q And, Dr. Miller, have you ever seen	16	MR. CLEMENT: 289957.
17	this document before?	17	MR. KENNEDY: 957.
18	A I have.	18	MR. CLEMENT: I'm sorry.
19	Q Can you identify it for the record?	19	MR. KENNEDY: Thank you.
20	A This is the third report of the	20	MR. CLEMENT: I misspoke. Thank you.
21	national cholesterol education program expert	21	BY MR. CLEMENT:
22	panel on detection, evaluation and treatment of	22	Q And that's a discussion of ApoB?
23	high blood cholesterol in adults, also known as	23	A Yes.
24	the adult treatment panel III, final report.	24	Q And it says there that ApoB is a
25	Q And this is a this was an exhibit to	25	potential marker for all atherogenic lipoproteins;
	Page 123		Page 125
1	your opening declaration; right?	1	right?
2	A I believe	2	A Yes.
3	Q If you can look at paragraph 13 of your	3	
4			Q What are atherogenic lipoproteins?
	report, that might help you.	4	Q What are atherogenic lipoproteins? A All lipoproteins besides HDL.
5	report, that might help you. A I think part of it was, but	4 5	
5 6		5	A All lipoproteins besides HDL.
	A I think part of it was, but	5	A All lipoproteins besides HDL. Q Okay. And this is saying it's a
6	A I think part of it was, but Q Not paragraph 13. I'm sorry. Page 13.	5	A All lipoproteins besides HDL. Q Okay. And this is saying it's a potential marker for those; right?
6 7	A I think part of it was, but Q Not paragraph 13. I'm sorry. Page 13. A Yes.	5 6 7	A All lipoproteins besides HDL. Q Okay. And this is saying it's a potential marker for those; right? A Yes.
6 7 8	A I think part of it was, but Q Not paragraph 13. I'm sorry. Page 13. A Yes. Q Okay. And in on page 13, you you	5 6 7 8	A All lipoproteins besides HDL. Q Okay. And this is saying it's a potential marker for those; right? A Yes. Q And that's what it was in 2009; right?
6 7 8 9	A I think part of it was, but Q Not paragraph 13. I'm sorry. Page 13. A Yes. Q Okay. And in on page 13, you you define that report, what we've marked as Miller	5 6 7 8 9	A All lipoproteins besides HDL. Q Okay. And this is saying it's a potential marker for those; right? A Yes. Q And that's what it was in 2009; right? A Yes.
6 7 8 9	A I think part of it was, but Q Not paragraph 13. I'm sorry. Page 13. A Yes. Q Okay. And in on page 13, you you define that report, what we've marked as Miller 15, as the operative report discussing lipid	5 6 7 8 9	A All lipoproteins besides HDL. Q Okay. And this is saying it's a potential marker for those; right? A Yes. Q And that's what it was in 2009; right? A Yes. Q And then it says a couple of sentences
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02/15/2018 126 to 129 Page 126 Page 128 1 measures are not widely available and in any case triglyceride-rich particle or microprotein which would add expense beyond routine lipoprotein is VLDL. 2 3 analysis. 3 So you're just saying here that if you Would you agree with that statement as measure lipid levels in the fasting state, you're 4 5 of 2009 time period? likely not to have chylomicrons? 6 As -- as the -- yes, as -- as the way Well, generally, yes. 7 it was written, I would. 7 Q And that's what you're trying to convey 8 Okay. We can put that away right now. here? 9 I think in your report you also talk 9 10 about chylomicrons. 10 Okay. All right. Are elevated -- in 11 Α Yes. 2009, were elevated levels of triglycerides What are chylomicrons? associated with atherosclerosis? 12 MR. KENNEDY: Object. 13 Chylomicrons are basically a -- fat 13 14 particles that occur after diet ingestion of 14 THE WITNESS: To a point. fat -- dietary ingestion of fat. BY MR. CLEMENT: 15 15 16 And, I guess, you know, one -- if you 16 0 What do you mean "to a point"? 17 turn to paragraph 31 of your declaration, and 17 To a point. Elevated levels are 18 maybe it's just the way I'm reading it but just 18 viewed -- elevated levels of triglycerides tend to 19 trying to get some clarity on something. be viewed as associated with atherosclerosis until 20 The last sentence of that paragraph 20 you get to very high levels. 21 says, Lipid levels are -- lipid levels are 21 So there is a distinction that the 22 typically measured in the fasting state in order 22 writers of ATP III going back to the 1980s -- well 23 to eliminate chylomicrons which are highly 23 known for a person of ordinary skill in the art variable in the circulation based on dietary who treats patients with lipid disorders; that as 24 24 25 intake of fat. triglycerides get into the very high range, Page 127 Page 129 1 Do you see that? they're susceptibility to atherosclerosis is Α No. What page are you talking to? reduced, whereas the -- the likelihood toward or 3 0 Are you on paragraph 31? the risk of pancreatitis goes up. Α Oh, paragraph 31. So, I guess, what levels -- when you

5 0 Sorry. 6 And I'm just looking at the last 7 sentence. 8 My question is how does measuring lipid 9 levels in the fasting state eliminate chylomicrons, or am I misreading the point you're 10 making? 11 12 So after you have a meal that contains 13 dietary fat, depending on how much fat you 14 consume, that fat gets processed into chylomicrons 15 which enter into the circulation shortly after you have a fat meal, peaks in the circulation 16 17 somewhere in terms of triglyceride levels -- peaks 18 somewhere at about four hours and then over time 19 generally gets metabolized out. That's why you 20 tend to have a higher triglyceride level after you 21 eat dietary fat, and that is related to 22 chylomicron uptake. 23 But if you look at the fasting state,

then you're presumably ridden of chylomicrons.

And you're honing into the other primary

24

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say "very high range," as the triglycerides get into the very high range, what range are you referring to there? Α About 500. About 500? 0 About 500 starts to set the stage. So about 500 triglycerides are not Q associated with atherosclerosis? MR. KENNEDY: Object to the form. THE WITNESS: I didn't say that. BY MR. CLEMENT: Okay. Then maybe I misunderstood. 0 That's why I'm asking the question. Above 500, the level is still up. as you continue to go up there's what we refer to as an inverted U-shape distribution as it relates to triglycerides in cardiovascular disease. And anybody who treats patients with lipid disorders and treats high triglycerides would appreciate that at very high triglyceride

levels, somewhere probably about 800 to a

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	Page 130				_	132
1	thousand we say 500, but clearly that that	1	the risk of pancreatitis goes up a	approxim	nately	
2	risk is still increased but it starts to go	2	4 percent.			
3	down as we move up closer to 800 to a thousand.	3	So not everybody that l	nas a		
4	Q So what risk goes starts to go down	4	triglyceride of a thousand will de	evelop a	ì	
5	as you get to 800	5	pancreatitis, but there is an inc	reased r	risk.	
6	A Well, cardiovascular.	6	Q So is it that above 50) the ri	isk of	
7	Q Cardiovascular?	7	pancreatitis becomes greater than	the ris	sk of	
8	A Cardiovas some it peaks	8	atherosclerosis?			
9	somewhere in the 2- to 600 range and then starts	9	A If the triglyceride ge	s to a	level	of
10	to go down. It's not a continuum risk as LDL	10	nearing approximating a thousand.			
11	level is. It's different.	11	Q Okay.			
12	Q So even below 500, triglycerides are	12	A Eight even 800 I	would s	sav	
13	associated with atherosclerosis?	13	starting somewhere in that 800 to		-	
14	MR. KENNEDY: Objection.	14	range.	G 0110 G	701101	
15	THE WITNESS: The risk of	15	Q Now, do you			
16	atherosclerosis probably starts to go up somewhere	16	Now, in paragraph 35 o	Frour	ronort	
17	in the hundreds.	17	I think this is kind of what we we	-	-	
18	BY MR. CLEMENT:	18	about that once the triglycerides	•		-
19			~ ·			
	ž	19	below the critical level and yo	nu say a	about :	500
20	treat if they get a patient who has a level of 350	20	mgs per dl?			- 7
21	triglyceride? Is that something they want to	21	A Right. And the adult		_	eı
22	treat to help prevent atherosclerosis in the 2009	22	basically made those cut points for			
23	time frame?	23	Q But here you say "about	_		
24	MR. KENNEDY: Objection to form.	24	A Yeah, about. I mean,			
25	THE WITNESS: And and this is where	25	a so generally speaking, trigly	/Cellues	are i	IIOC
	Page 131				Page	133
1	we've begged to have a clinical trial to look at	1	a primary treatment for clinicians	unless	leve	ls
2	this. It had not been looked at in the way that	2	exceed 500. Then it becomes the p	primary	thera	ру
3	we had been hoping for, and that is to design a	3	in order to lower those triglycer:	ides and	1	
4	clinical trial where you're looking at patients	4	presumably reduce their risk.			
5	that have a triglyceride in that sweet spot of	5	Q Do you treat a patient	who pre	esents	to
6	atherosclerosis, which is somewhere in the 200 to	6	you with a triglyceride level of	195 diff	erent:	ly
7	500 range, that sweet spot, to determine whether	7	than you treat one who has a level	of 501	?	
8	low triglycerides in that range on top of standard	8	A Yeah.			
9	of care therapies reduces the risk of	9	MR. KENNEDY: Objection	n to for	rm.	
10	cardiovascular events. Hence Amarin steps up to	10	THE WITNESS: So, again	n, the r	number	
11	the plate and does the study.	11	there is gives you and gives a	ny perso	n who	
12	BY MR. CLEMENT:	12	treats patients some reference to	use. '	These	are
13	Q At about 500?	13	quidelines, and if you treat patie	ents, yo	ou wou.	ld
14	A No, we're now talking about between 200	14	come up with kind of an idea of wh	no the r	atient	t
15	to 500, the REDUCE-IT study. That's the study.	15	which patients pose most risk.	-		
16	Q Okay.	16	So am I going to diffe:	rentiate	e betw	een
17	A 500 is pancreatitis above 500 we're	17	a 499 and a 501 of course not.			
18	talking about pancreatitis. Below 500 200 to	18	puts me in the ballpark of where i			
19	500 is really the sweet spot of atherosclerosis.	19	bit concerned with respect to that			
20	Q So above 500, you're really worried	20	high triglycerides than I would be			-
21	about pancreatitis; is that	21	was 100.	- 11 (11)	. 1000.	-
22	A So the way the way it works is that	22	BY MR. CLEMENT:			
23	the numbers you know, you take and these are	23	Q So if you turn to the	natent	the "	728
24	approximations for each 100-milligram per	24	patent which I think you have the		CIIC	, 20
1 44	abbrovingeroup for each ton-mittitation ber	44	Paccife mitter t cittin you have the			

25 deciliter increment above 500, give or take again, 25 A I do.

D 105
Page 136
t there on yours.
u cite in that
y. Let's mark as
with Bates range
n Exhibit 16 was
d attached to the
Miller, I'll
he that's the
ration that's
story.
ou cited to in
right?
to the first one,
hich is at 3059121.
ay. And that's the
hat you relied on;
Page 137
d a magnifying glass,
a a magnirying grass,
the way it's printed.
page 9123 for a
you see it says,
/Ou see It says,
2000 3-1
2009 date; correct?
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ection to form.
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ection ht. Bu

	0	2/15/2	018 138 to 141
		e 138	Page 140
1	Q You did not rely on an earlier ver	sion 1	A Okay.
2	for your declaration; right?	2	Q package inserts that you discussed
3	A That is correct.	3	in paragraph 37 of your declaration.
4	Q And you rely specifically on page	2 of 4	A Uh-huh.
5	this package insert, right, which is at 9121?	5	Q Okay. And this one is for Lopid;
6	A Yes.	6	right?
7	Q That's what you cite to 9121 is	what 7	A Yes.
8	you cite to in paragraph 37 of your declarati	on; 8	Q Which is gemfibrozil?
9	right?	9	A Correct.
10	A Correct.	10	Q And if you turn to page 118, the bottom
11	Q Do you recall what exactly you wer	e 11	left, do you see it's a 2000 September 2010
12	relying on on 9121?	12	document?
13	A Let's see what it says here.	13	A I see that.
14	(Witness reviews document.)	14	Q That's after the 2009 date; right?
15	So I have to look at these tables.	It 15	A That's what it says.
16	would be nice to	16	Q So this document would not have been
17	(Witness continues reviewing docum	ent.) 17	available to the person of ordinary skill in the
18	So there's one table here in	18	art in 2009; right?
19	patients in Table 2 where LDL levels go up	from 19	A Well, I don't know. If you look at
20	baseline of 120 to a baseline of 128, and the	n 20	page 100, it says revised July 2001. So I'm not
21	right below that are baseline LDL levels in -	- 21	sure it says additional adverse reactions have
22	with triglycerides of 5- to 1500 where LDL go	es up 22	been reported including cholecystitis and
23	45 percent.	23	cholelithiasis. To me, that suggests that only
24	Q But this this this product,	24	that paragraph on page 101 was from 2010, but the
25	TriCor, it's not contraindicated in people wi	th 25	one from 100 was revised in 2001, and everything
	Pag	e 139	Page 141
1	Pag VHTG; right?	e 139	Page 141 preceding that would be related to 2001 time
1 2			
	VHTG; right?	1	preceding that would be related to 2001 time
2	VHTG; right? A I it is not contraindicated in	1 2 3	preceding that would be related to 2001 time frame.
2 3	VHTG; right? A I it is not contraindicated in people with VHTG.	1 2 3	preceding that would be related to 2001 time frame. Q What page are you on?
2 3 4	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i	1 2 3 s to 4	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118
2 3 4 5	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high	1 2 3 s to 4 5	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right.
2 3 4 5 6	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high triglyceride levels will in and of itself be	1 2 3 s to 4 5 6	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At
2 3 4 5 6 7	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic.	1 2 3 s to 4 5 6 7	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001.
2 3 4 5 6 7 8	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic. Q Okay. But, again, it's not	1 2 3 s to 4 5 6 7 8	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001. So my interpretation would be that
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2 3 4 5 6 7 8 9	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic. Q Okay. But, again, it's not contraindicated A No.	1 2 3 s to 4 5 6 7 8 9 10	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001. So my interpretation would be that unless there are other revisions above that that everything related to Exhibit B, Lopid, through
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2 3 4 5 6 7 8 9 10 11	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal i try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic. Q Okay. But, again, it's not contraindicated A No. Q and you prescribe it with peopl with VHTG; right?	1 2 3 s to 4 5 6 7 8 9 10 e 11 12 13	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001. So my interpretation would be that unless there are other revisions above that that everything related to Exhibit B, Lopid, through page 9117 would would be valid through July 2001; and then the additional wordage
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2 3 4 5 6 7 8 9 10 11 12 13 14	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal it try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic. Q Okay. But, again, it's not contraindicated A No. Q and you prescribe it with people with VHTG; right? A Yes. Q Okay. Let's go to the next label	1 2 3 s to 4 5 6 7 8 9 10 e 11 12 13 for 14 15	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001. So my interpretation would be that unless there are other revisions above that that everything related to Exhibit B, Lopid, through page 9117 would would be valid through July 2001; and then the additional wordage regarding the additional changes and adverse reactions were added in, and that revision came
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	VHTG; right? A I it is not contraindicated in people with VHTG. Remember, though, the first goal is try to reduce the likelihood that very high triglyceride levels will in and of itself be problematic. Q Okay. But, again, it's not contraindicated A No. Q and you prescribe it with people with VHTG; right? A Yes. Q Okay. Let's go to the next label Lopid, 305 page 9106. A And and I I should say that prescribe in 2009, right, at the time of we talking about when these prescriptions Q Okay. A When we talk about prescriptions as	1 2 3 s to 4 5 6 7 8 9 10 e 11 12 13 for 14 15 I 16 e're 17 18 19 s 20	preceding that would be related to 2001 time frame. Q What page are you on? A If you look at page 9118 Q Right. A so that said now go to 9117. At the top of 9117 it says, Revised July 2001. So my interpretation would be that unless there are other revisions above that that everything related to Exhibit B, Lopid, through page 9117 would would be valid through July 2001; and then the additional wordage regarding the additional changes and adverse reactions were added in, and that revision came through in September of 2010. Q Okay. But we don't know because we don't have the 2001 label here; right? A Well, but it says, Revised July 2001, incorporating all all this information. So to me it would seem that all this
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		02/15	720	018	142 (145
		Page 142			P	age	144
1	A	Rhabdomyolysis.	1	Q I'm sorry. Go ahead.	Finish.	I	
2	Q	Thank you.	2	didn't mean to speak over you.			
3		When combined with a statin; right?	3	A And			
4	A	Correct.	4	Q I mean, we can look			
5	Q	Okay. If we turn to page 110 of this	5	A That's what I'm			
6	document i	in the contraindications section, it only	6	Q We can look at page 15	9, and tha	at 20	010
7	lists one	statin, right, in the contraindication	7	date is also there; right? And w	e can loo	k at	on
8	section; o	correct?	8	163, and that 2010			
9	A	Combination of therapy with	9	A Right.			
10	cerivastat	tin due to the increased risk of myopathy	10	Q date is there?			
11	and rhabdo).	11	So this document itsel	f, right,	that	t
12	Q	And cerivastatin, that was a Bayer	12	you were relying on, this wasn't	this do	ocume	ent
13	drug?		13	was not available to the person o	f ordinary	, ski	ill
14	А	That's correct.	14	in the art in 2009; right?			
15	Q	Baycol?	15	A Well, not the way it i	s written		
16	А	Correct.	16	And and for for all intents	and purpo	ses,	,
17	Q	No longer on the market; right?	17	there may have just been one para	graph that	was	S
18	А	Correct.	18	revised. I have to look at the 2	009		
19	Q	And no other medications statins are	19	Q But you didn't provide	us the 2	009	
20	indicated	in the contraindications; right?	20	label; right?			
21	А	None were identified in the	21	A I did not.			
22	contraindi	ications; although, I will tell you for	22	Q Okay. And you didn't	rely on ti	he 20	009
23		ating patients in this time frame that it	23	label in your paragraph 37; right	-		
24		a concern combining Lopid with any	24	this one?			
25	statin.	J 1	25	A (Witness reviews docum	ent.)		
		Page 143			F	age	145
1	Q	Okay. But that's not what it says here	1	I relied on this (indi	cating) d	ocume	ent.
2	in the cor	ntraindications	2	Q Okay. Is there anythi	ng in thi	S	
3	A	No	3	document that says you shouldn't	treat pat:	ients	3
4	Q	right?	4	with triglyceride levels of 500 t	o 1500 mgs	s per	r dl
5	А	that's true.	5	with Lovaza?			
6	Q	There are other statins out there;	6	MR. KENNEDY: Objection	n to form		
7	correct?		7	THE WITNESS: No.			
8	A	That's correct.	8	But, again, we have to	put thing	gs ir	n
9	Q	And some of them metabolize or interact	9	perspective, and that perspective	is when a	a	
10	with drugs	s differently?	10	patient has very high triglycerid	e, the fir	rst	
11	A	Yes.	11	order of treatment is to lower VH	IG, and th	nen f	Erom
12	Q	Kind of like the pitavastatin you were	12	there we take additional steps.	But the f	irst	
13	mentioning	g this morning that you were involved in?	13	order is to lower the triglycerid	е.		
14	A	That's correct.	14	BY MR. CLEMENT:			
15	Q	Okay. Let's turn to 3059150, the next	15	Q Okay. And if you look	you r	ely o	on
16	one, Lovaz	za. And if you look on page 9150, it	16	page 157; right? And this is tal	king abou	t	
17	says, Revi	ised: December 2010.	17	patients with very high triglycer	ide levels	s, ak	oove
18	A	I see that.	18	500 mgs per dl; right?			
19	Q	So this one also was not available to	19	A Yes.			
20	the persor	n of ordinary skill in the art in 2009;	20	Q It doesn't say don't t	reat patie	ents	
21	correct?		21	with Lovaza. All it says is pati	ent should	d be	
22	A	Well, again, it's unclear to me what	22	monitored; right?			
23	was revise	ed in 2010.	23	A Yes.			
1	Q	Well, if you go	24	Q Now let's look at Nias	pan, 3059	139.	
24	Q						
24 25	A	And	25	Can you turn to 9139, please?			

Page 146 Page 148 1 MR. KENNEDY: It's back the other way. 1 is dated after 2009; right? BY MR. CLEMENT: 2 The document is dated after 2009. 3 Okay. And this is the fourth package Q Okay. Now --4 insert you rely on for paragraph 37; correct? Α -- I will agree. 5 -- let's look at the document. You 6 0 And this is also a 2010 revision relied on -- I guess, on -- you say in 7 document; right? paragraph 57 you rely on page -- I'm sorry. You 8 Α Yes. say in paragraph 37 of your declaration you rely 9 So this one wouldn't have been 9 on pages 139 to 148 of this document; right? 10 available to the person of ordinary skill of the 10 I'm just wondering what exactly in this art in 2009; correct? document you're relying on? 11 11 Well, again, I don't know that. We 12 If you'll give me just one minute to 12 Α review it. 13 know that there was clearly information that was 13 14 available, and the extent to which there might Q Sure. have been changes between 2009 or 2008 and 2010 Α 15 15 (Witness reviews document.) 16 whatever, previous version is, is -- is unclear. 16 So the discussion with respect to 17 Right. 17 niacin is the issues of the side effects, and 18 But, again, we don't know because you those issues are described on 146, 147, 148. 19 didn't provide that in your declaration; right? 19 But all drugs have side effects; right? 0 20 What you provided was a 2010 re- -- revision; 20 MR. KENNEDY: Object. 21 correct? 21 THE WITNESS: Niacin has side effects 22 Α That's correct. 22 that can be intolerable to patients, more than the 23 0 And the 2010 revision, the document 23 other triglyceride-lowering drugs. here that's before us on 9139 through 9148, that BY MR. CLEMENT: 24 24 25 was not -- this document as it exists here was not 25 Okay. They all -- again, all drugs Page 147 Page 149 available to the person of ordinary skill in the have side effects; right? 2 art in 2009; right? MR. KENNEDY: Same objection. 3 Well, the document wasn't -- may have THE WITNESS: There is a difference in not been in its exact form, but it was certainly tolerability of some drugs compared to others. recognized that LDL increases did exist with some Niacin often is not tolerated in a sizeable 6 of these agents including gemfibrozil, including percentage of patients whereas other medications 7 fenofibrate. And some of the side effects I've to treat very high triglyceride levels are. alluded to with niacin have been known well before BY MR. CLEMENT: 2009 -- well before then. Now --9 Right. But you didn't provide that So, yes, all drugs have side effects, 10 document to us. You provided a 2010 document that 11 11 but the degree and extent of side effects that may was after the date of the patent filing; right? 12 12 limit its usage is different. 13 Well, but, again, I can -- my 13 Okay. But it's not contraindicated 0 14 experience in this field dating back to the 1980s, 14 with patients who have VHTG; right? 15 I could verify that these problems existed well 15 No, it was -- at the time it was before this time frame. recommended for patients with VHTG. 16 16 17 You could have verified that before you 17 Q Okay. Now, you -- I think we talked 18 submitted your declaration or before you submitted earlier about Epadel? 18 19 your reply declaration and you didn't; correct? 19 Α Yes. 20 Well, I think part of the declaration 20 And that was a Japanese medication; 0 21 also attests to my level of experience in the 21 right? field which predates 2009. 22 22 Α That -- that was my understanding. 23 Understood. 23 Q Now, you don't cite to Epadel in your 24 But you relied on this document for declaration as all; right? 24 25 your statement in paragraph 37, and this document 25 Δ Correct. It's outside of the scope of

		02/15	, 20	J16 150 CO 153
		Page 150		Page 152
1	my declar	ation.	1	Q With a high purity?
2	Q	Why is it outside the scope of your	2	MR. KENNEDY: Same objections.
3	declaration	on?	3	THE WITNESS: I don't know what the
4	A	It just wasn't cited.	4	purity is.
5	Q	Okay. We did you not cite it	5	BY MR. CLEMENT:
6	because i	t was a Japanese drug instead of a U.S.	6	Q Now have you ever been involved in a
7	drug or -	-	7	clinical study?
8	A	I I really haven't given it that	8	A I have.
9	much thou	ght.	9	Q And have you ever drafted a clinical
10		MR. CLEMENT: Let's mark as Miller	10	protocol?
11	16		11	A I have not.
12		THE COURT REPORTER: Seventeen.	12	Q Do you know what the purpose of
13		MR. CLEMENT: 17, sorry, a document	13	A Oh, let let me take that back.
14	with defe	ndants Bates range 8961 through 8969.	14	Q Okay.
15		(Miller Deposition Exhibit 17 was	15	A Clinical could you be a little more
16	marked for	r identification and attached to the	16	specific?
17	transcrip	t.)	17	Q I guess I protocol for a clinical
18	BY M	R. CLEMENT:	18	study?
19	Q	Dr. Mill Dr. Miller, have you ever	19	A I've done studies but not drug-based
20	seen this	document before?	20	studies. Well, I take that back. I did do I
21	A	No.	21	did do an investigator initiated study a number of
22	Q	It's dated January 2007.	22	years ago, so I did draft that protocol.
23	A	I see that.	23	Q What so what is a protocol? What's
24	Q	It's indicated for hyperlipidemia,	24	the purpose of it?
25	page 2?		25	A Well, the purpose of a protocol is to
		Dago 151		Dago 152
1	А	Page 151 In Japan, I take it?	1	Page 153 really have set a set format and blueprint for
2	Q	Yeah.	2	how you would conduct a trial, and that would
3		Correct?	3	include a number of variables.
4	A	Yes.	4	Q Are there different types of studies
5	Q	And it says to increase the dose when	5	that you can conduct in the clinical as far as
6	excess tr	iglycerides are present; right?	6	a clinical study goes?
7		MR. KENNEDY: Objection: outside the	7	A Well, of course there are studies that
8	scope of 1	nis opinions.	8	are observational in nature whereas there are
9		THE WITNESS: It's outside the scope	9	studies that are treatment designed.
10		MR. KENNEDY: I mean	10	Q Okay. And what about, like, a
11		THE WITNESS: of my opinions.	11	double-blind study? Have you ever heard of that?
12		MR. KENNEDY: you can answer. I	12	A Yes.
13	have to m	ake my objections.	13	Q Okay. And, in fact, on your CV, I
14	BY M	R. CLEMENT:	14	think on page 12, you talk about a double-blind
15	Q	You can answer.	15	study.
16		MR. KENNEDY: You can answer if you	16	You can check on your CV.
17	can.		17	A Yes.
18		THE WITNESS: That's what it says.	18	Q What is a what does the "double"
19	BY M	R. CLEMENT:	19	refer to?
20	Q	And, again, Epadel was pure icosapent?	20	A Well, the double refers to maintaining
21		MR. KENNEDY: Objection to form;	21	a blinding status from both the standpoint of the
22	outside th	ne scope.	22	patient and the standpoint of the
23		THE WITNESS: It's ethyl	23	investigators/coordinators conducting the trial.
24	eicosapen	taenoic acid.	24	Q So and blind refers to what?
25	BY M	R. CLEMENT:	25	A Neither party knows whether the
23				

Page 154 Page 156 1 treatment is active or inactive. mean, how it is prescribed, right, because I haven't seen too many double-blind studies where 2 You don't know if you're taking the 3 medication or a placebo? there -- well, it could be injectable --4 Correct. 4 0 Okay. 5 And is that different than an 5 Α -- there are a lot of injectable open-label study? studies out there. 7 Α Yes. 7 Q That's fair enough. I'm talking about How is that different from an an oral. 8 9 open-label study? 9 Α Right. 10 In an open-label study, the medication 10 Q Okay. All right. What about a is provided and the patient and investigator parallel -- what's a -- I quess -- have you ever 11 generally know that the medication is being used. heard of a crossover study? Let's start there. 12 13 Right. 13 Α 14 And what about a placebo-controlled 14 Q Do you know what a crossover study is? study? Do you know what that means? 15 15 Α Yes. 16 I think in your -- on your -- on 16 0 Can you --17 your -- your CV you talk about double-blind and 17 Α A crossover study is when the 18 placebo-controlled. That's where I'm getting it 18 volunteers are assigned to more than one arm, and 19 from. 19 they crossover. So they will go on, let's say, 20 Right. A placebo-controlled study medication A for a period of time, have a washout 21 would be that the comparative nature includes the 21 period, then medication B for a period of time, active compound versus the inactive compound. 22 22 have a washout. 23 In order to have an inactive compound, 23 And that's usually what we refer to as randomized and counterbalanced which means that 24 some of the subjects of the study are actually 24 the volunteer doesn't know which phase -- which 25 taking a pill that have -- just doesn't have Page 155 Page 157 medicament in it; correct? medication, and it's counterbalanced so that if 1 2 Yeah, ideally you'd want to take -- for you look at 50 subjects, 25 of them get medication 3 all intents and purposes, you would want the shell A first, and 25 of them will get medication B to resemble each other -- of course the shell first. being inactive whether it's pharmaceutical grade 5 When you said there's two arms, what do 5 6 or nonpharmaceutical grade, but the composition you mean by the arms? 7 inside is what differentiates. The arms is -- is really that portion 8 The person doesn't know looking at it of the study where that assignment of medication from the outside whether they have the placebo on is -- is identified or blinded, if you will. 9 9 the one hand or the active medication in the 10 And is that different than a parallel 10 Q other; right? 11 11 study? 12 Α 12 Yeah, I don't do -- I've not really 13 But they're actually -- even the ones participated too much in parallel studies. 13 14 who are the controlled part of the study getting a 14 I think on page 16 of your CV you talk 15 placebo, they're actually swallowing a pill? 15 about a grant that was a -- it says, Parallel Well, the -- whether it's in a clinical group. So, I don't know, maybe that wasn't a 16 Α 16 17 trial or in practice, it's more than just 17 parallel study. Maybe I'm misreading --18 swallowing a pill. It's being advised what to 18 That's not a parallel study. Α take and when to take it, so it's administering 19 19 What did you mean by "parallel group" 0 from the caregiver. And ultimately one part of 20 there, though. Do you see that one, April 2005 to 2.0 21 that process is that the patient or the subject if 21 March 2007?

Yes, I -- I -- I think it's just

running them in parallel, so you're having

receiving the atorvastatin only arm.

patients receiving either the combination arm or

22

23

24

it's a clinical trial will take the pill -- will

If -- if it is -- depending upon, I

Swallow the pill, okay.

22

23

24

25

swallow the pill.

Q

Α

	02/15	, – •)18 158 to 161
	Page 158		Page 160
1	Q So they're not crossed over? You get	1	don't do that after you conduct the study; you do
2	one	2	that before?
3	A They're not	3	MR. KENNEDY: Objection to form.
4	Q arm or the other?	4	THE WITNESS: Yeah, in some trials they
5	A crossed over; correct.	5	actually have what we call an interim analysis.
6	Q Okay. I guess, what knowledge do	6	So you can make some changes although that that
7	you consider you're an ex strike that.	7	adversely affects your power I mean, that
8	Do you consider yourself an expert in	8	adversely right, so that does that does
9	statistics?	9	exist.
10	A No.	10	BY MR. CLEMENT:
11	Q Okay. Do you consider yourself	11	Q Okay. Is that something you'd use a
12	knowledgeable about statistics?	12	Bonferroni correction for? Do you know what a
13	MR. KENNEDY: Objection to form.	13	Bonferroni correction is?
14	THE WITNESS: I usually will confer	14	A Yeah, I've seen Bonferroni, but I think
15	with a statistician in regard to studies that are	15	it's somewhere along in that ballpark.
16	conducted. Interpreting results of studies, I	16	Q And does the type of statistics a
17	have some basic knowledge.	17	statistician will use will depend on whether the
18	BY MR. CLEMENT:	18	data is normal or not normal?
19	Q Do you know what the concept of	19	A Yes.
20	statistical significance is?	20	Q Do you know why they use different
21	A Yes.	21	tests?
22	Q Okay. What is that to you?	22	A Yeah. Well, you know, in the sense
23	A Well, it's usually related to trying to	23	of depends on if there's a normal distribution.
24	determine whether or not group A is different from	24	So if if the distribution is is abnormal or
25	group B, and oftentimes a study is powered to show	25	highly variable, they may need to kind of tighten
25	group b, and orcentimes a study is powered to snow	25	mighty variable, they may need to kind of tighten
1	Page 159 that there's a significant difference of less than	1	Page 161 it up. And, so, they may use different forms of
2	or equal to 5 percent which means less than	2	stats such as log transformation is one way to
3	5 percent of the time you would see expect to		
4		3	tighten it up.
1 4	see virtually the same value.	3 4	tighten it up. Q Or Mann-Whitney?
5	see virtually the same value. Q Okay. And do you know what a		2
	•	4	Q Or Mann-Whitney?
5	Q Okay. And do you know what a	4 5	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of
5	Q Okay. And do you know what a confidential interval is?	4 5 6	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different
5 6 7	Q Okay. And do you know what a confidential interval is? A Yes.	4 5 6 7	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch
5 6 7 8	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval?	4 5 6 7 8	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones.
5 6 7 8 9	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic	4 5 6 7 8	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right.
5 6 7 8 9	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent,	4 5 6 7 8 9	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit
5 6 7 8 9 10	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will	4 5 6 7 8 9 10	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a
5 6 7 8 9 10 11 12	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range.	4 5 6 7 8 9 10 11	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary
5 6 7 8 9 10 11 12 13	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're	4 5 6 7 8 9 10 11 12 13	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable?
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5 6 7 8 9 10 11 12 13 14	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You	4 5 6 7 8 9 10 11 12 13 14 15	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want
5 6 7 8 9 10 11 12 13 14 15	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined	4 5 6 7 8 9 10 11 12 13 14 15	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that.
5 6 7 8 9 10 11 12 13 14 15 16	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're	4 5 6 7 8 9 10 11 12 13 14 15 16	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes.
5 6 7 8 9 10 11 12 13 14 15 16 17	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's	4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you.
5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you. A And it depends on the specific study
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not? A As a general rule, you would	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you. A And it depends on the specific study you're looking at. But primary efficacy well,
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not? A As a general rule, you would predetermine you would power the study so that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you. A And it depends on the specific study you're looking at. But primary efficacy well, there are lots of different outcomes you could
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not? A As a general rule, you would predetermine you would power the study so that a statistician will do a calculation to determine	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you. A And it depends on the specific study you're looking at. But primary efficacy well, there are lots of different outcomes you could talk about. In early phase trials you're looking
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Okay. And do you know what a confidential interval is? A Yes. Q What is a confidence interval? A Confidence interval tells you the basic branch points of a study, so if it's 95 percent, you could be 95 percent sure that the data will fall within a step range, specific range. Q And when you say that when you're looking at statistical significance, that's usually predefined what that level will be. You said 95 percent. Is it pre usually predefined in the medical protocol what that level you're looking for is to determine whether it's statistically significant or not? A As a general rule, you would predetermine you would power the study so that a statistician will do a calculation to determine the number of participants needed to see a	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Or Mann-Whitney? A Or Mann-Whitney. There are a bunch of different Q Bunch A ones. Q of ones, right. And I think we talked a little bit earlier that in a study typically it might have a primary efficacy variable and a secondary variable? A (Witness nods head.) Q I think nods of the head I just want to make sure the court reporter is getting that. A Yes. Q Thank you. A And it depends on the specific study you're looking at. But primary efficacy well, there are lots of different outcomes you could talk about. In early phase trials you're looking at safety and efficacy. In more advanced stages

Page 162 Page 164 1 the blood pressure -- a degree of blood pressure 1 I quess, you know, you say here they 2 lowering that might be anticipated. At higher cover this, and they say to very high TG patients 3 stages you might look to see patients with blood receiving diet and lifestyle-change counseling. And, I guess, where did you get that 4 pressure being placed on blood pressure medication 4 5 A versus B may have a -- a reduction in from, receiving diet and lifestyle-change cardiovascular events. counseling? 7 And might you use different 7 Α Yes, so that was part of the MARINE significance levels for each of those different study. In the MARINE study, patients get -- being 8 9 variables that you might look at? Is it always 9 considered for inclusion into the study needed to 10 going to be .05 or -be first placed on a diet and lifestyle change. 11 Yeah, it varies. I mean, typically --So they received counseling, and they received the traditionally in outcome studies .05 is the therapeutic, lifestyle-change counseling. 12 number, but it does vary. And if you're doing Okay. That was in the studies. Do you 13 13 14 genetic studies, then sometimes it goes out to the equate the patent and the study? order of magnitude of up to minus ten -- fifth to 15 MR. KENNEDY: Objection to form. 15 16 tenth power, so it depends on a lot of variables 16 THE WITNESS: No, a patent is -- is -that -- that statisticians are familiar with. 17 17 relies upon the study, but -- and the results 18 Okay. Let's turn to paragraph 39 of obtained in the study in formulating the patent. 19 your report. And in paragraph 39 -- are you 19 But a study and the patent are not one and the 20 there? 2.0 same. 21 Α I am here. 21 BY MR. CLEMENT: 22 0 Great. 22 Okay. Because in claim 1 or any of the 23 The third sentence you say, The methods 23 claims in the '728 or any of the patents-in-suit, developed by the inventors covered administering a does that language exist, "diet and 24 25 lifestyle-change counseling"? high dose, 4 grams per day. Page 163 Page 165 1 I'm sorry. I'm on -- is it -- I'm 1 MR. KENNEDY: Objection to form. looking at page 39, but you're looking at --THE WITNESS: I would have to review 3 Sorry. Paragraph 39. that. 4 Α Paragraph 39. BY MR. CLEMENT: 5 Well, take a look at at least the '728 Sorry. 6 Okay. You see the third sentence patent since we have that here. 7 begins, The method -- methods developed by the 7 Right. So if we look at claim 1 in the 8 inventors covered, and it goes on? '728 patent, the focus here is on concomitant 9 (Witness nods head.) lipid-altering therapy, which would not be 9 Okay. What did you mean by "covered"? inclusive of lifestyle therapy. It's distinct 10 Is that what the inventors claimed? I because lifestyle therapy had already been 11 11 guess that's the question I'm trying to get to. instituted, at least -- everybody goes on 12 12 13 Yeah, I think I'm -- the methods 13 lifestyle therapy. That -- that's a given. And, 14 developed by the inventors covered administering so, this is beyond that point. It's patients that 15 this dose to very high TG patients. have residual triglyceride elevation between 5- to Yeah, covered was -- that's how they 16 1500. 16 17 solve the problem which is noted two sentences up. 17 Okay. So you're saying that everyone 18 Okay. Is that what they claimed, or in claim 1 was on lifestyle therapy; is that what 18 19 was it something different? 19 you're saying? 20 Well, the claimed composition is 20 MR. KENNEDY: Objection to form. 21 discussed a little bit beforehand, but in terms 21 THE WITNESS: I'm not -- I'm referring of -- of covered, I think I was referring to to everybody in the MARINE study who participated 22 22 23 basically the administration of this medication 23 in that clinical trial were placed on diet and that would result in -- in some of the changes 24 24 lifestyle therapy in order to determine whether

they would still be potentially eligible to

here related to TG and ApoB.

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Page 166
                                                                                                         Page 168
 1
    participate in the trial.
                                                                          THE WITNESS: So it really does depend
          BY MR. CLEMENT:
 2
                                                               on the clinical scenario. So as I've said, they
 3
                I think we're in agreement on that.
                                                               automatically -- they all go on it, and then
                But I guess my question is for the
 4
                                                               question is are we also going to institute
5
     claim, right -- is this claim trying to claim what
                                                               pharmacologic measures at that time. So I think
 6
     was in that example?
                                                               that's maybe where that --
 7
                MR. KENNEDY: Objection to form.
                                                           7
                                                                    BY MR. CLEMENT:
 8
                THE WITNESS: It's really looking at
                                                                          Okay. But, again --
9
    patients and -- and my -- my interpretation is
                                                           9
                                                                          They all go on -- they all go on
10
     that it is looking at patients who we encounter in
                                                          10
                                                               lifestyle therapy.
     practice who have a fasting baseline level in this
                                                                          Including those with triglyceride
11
                                                          11
                                                                    Q
    range, viewed in the very high triglyceride range.
                                                               levels above 500 mgs per dl?
12
                                                          12
         BY MR. CLEMENT:
                                                                          They all go -- I refer to it as a
13
                                                          13
14
                So in the patients who you encounter,
                                                               therapeutic lifestyle change. It's something
     they may or may not be on a lifestyle counseling,
                                                               that's not unique. It's broad-based. It's for
15
16
    right, the first time you see them?
                                                          16
                                                               any patient. And it's different than blood
17
                Correct.
                                                          17
                                                               pressure therapy, blood pressure medication,
18
                Right.
                                                               lipid-lowering therapy, lipid-lowering medication,
19
                And the first therapy -- the first line
                                                               hypoglycemic agents, glucose-lowering therapies.
                                                          19
20
    of therapy, am I correct, would be put them on
                                                          20
                                                                          I understand all of that.
21
     some sort of diet and exercise regimen?
                                                          21
                                                                          I guess my question to you, though,
22
                MR. KENNEDY: Objection to form.
                                                          22
                                                               remains, the person who comes in and their lipid
23
                THE WITNESS: The first line of therapy
                                                          23
                                                               levels are -- they have a triglyceride level of
    for any patient we see -- it doesn't have to be
                                                               500 -- more than 500 mgs per dl. The first thing
24
25
    very high triglyceride patient; it's any patient
                                                               you're going to -- the first form of therapy that
                                               Page 167
                                                                                                         Page 169
     that we would see -- we're going to recommend
                                                               you're going to tell them to do is to go on some
     lifestyle therapy.
                                                               sort of diet and exercise regiment; correct?
3
                So it doesn't matter if they're -- what
                                                                          MR. KENNEDY: Objection to form.
     they're -- if their triglyceride is normal or
                                                                          THE WITNESS: Yeah. You know, I look
     abnormal. They may have high -- some degree of
                                                               at it as a lifestyle change.
5
 6
     elevated blood pressure. They're going to go on
                                                                    BY MR. CLEMENT:
 7
     lifestyle therapy. They may have some degree of
                                                                          Okay.
8
     elevated blood glucose. They're going to go on
                                                                    Α
                                                                          It's a lifestyle change.
     lifestyle therapy. They may have some degree of
9
                                                                    0
                                                                          Okay.
    obesity and want to lose weight. They are going
                                                                          That's what it is.
10
11
     to go on lifestyle therapy.
                                                          11
                                                                          That's fair enough. Okay.
                The point being that "lifestyle
12
                                                          12
                                                                          Now, you say here in 39, also -- you
13
     therapy" is a very broad term. Patients should go
                                                          13
                                                               talk about the claimed composition. I mean, I
14
    on lifestyle therapy. Did -- it's -- it's really
                                                               guess, I just want to make sure we're on the same
15
     initial management of any patient that has any
                                                          15
                                                               ballpark. My understanding is all the
    cardiovascular risk factor.
                                                               patents-in-suit, they claim a method of treating;
16
                                                          16
          BY MR. CLEMENT:
17
                                                          17
                                                               right?
18
                But that includes VH -- VHTG patients
                                                          18
                                                                    Α
                                                                          Yes.
19
     that present to you. The first thing you'll do
                                                          19
                                                                    Q
                                                                          Okay. They're not claiming the
20
     for therapy is put them -- give them ther- --
                                                          20
                                                               composition, per se?
21
     lifestyle counseling, right --
                                                          21
                                                                    Α
                                                                          No.
22
                MR. KENNEDY: Objection.
                                                          22
                                                                    0
                                                                          Right.
23
         BY MR. CLEMENT:
                                                          23
                                                                    Α
                                                                          It's method of treatment.
24
                -- diet and exercise regime?
                                                          24
                                                                    Q
                                                                          Okay. Now, also if you look at claim 1
25
                MR. KENNEDY: Objection to form.
                                                          25
                                                               of the '728 patent --
```

```
Page 170
                                                                                                           Page 172
 1
          Α
                Yes.
                                                            1
                                                                           I may -- I may -- it depends.
 2
          Q
                -- and do you see about one, two,
                                                                depends on the scenario. Certainly if they're
 3
     three, four, five lines down in that claim there's
                                                                coming to see me and they have a history of
     the term "pharmaceutical composition"?
                                                                pancreatitis and they're not taking any medication
 4
5
          Α
                                                                at that time, I'm going to put them on
 6
                All right. Do you have knowledge as to
                                                                medication --
 7
     whether the parties are disputing the meaning of
                                                            7
                                                                     Q
8
     that term?
                                                                     Α
                                                                           -- at that time --
 9
                I don't believe I commented that in
                                                            9
                                                                           And --
10
                                                           10
                                                                     Α
                                                                           -- triglyceride-lowering medication.
    mv --
                All right. That's going to be my next
                                                                           And could that include statins?
11
          Q
                                                                     Q
                                                                           Probably not.
12
    question.
                                                                     Α
13
          Α
                Yeah.
                                                           13
                                                                     0
                                                                           Probably not, okay.
14
                I mean, have you given any opinions on
                                                           14
                                                                     Α
                                                                           Not in that specific scenario. Now,
    the term "pharmaceutical composition" in your
                                                                there are other scenarios where that might be the
15
16
    declaration?
                                                                case, but not the one we just discussed.
                I don't believe so.
17
                                                           17
                                                                           Okay. But there are cases where you
18
          0
                And in your reply declaration?
                                                           18
                                                                might prescribe statins; right? That would be --
19
                I don't believe so.
                                                                I guess, my question -- do you agree with me that
20
                And you weren't asked to give opinions
                                                                statins would be a concomitant lipid-altering
21
    by counsel on the term "pharmaceutical
                                                           21
                                                                therapy?
22
     composition" --
                                                           22
                                                                           MR. KENNEDY: Objection to form.
23
          Α
                I am not --
                                                           23
                                                                           THE WITNESS: It is a concomitant
                -- right?
                                                                lipid-altering therapy as -- as stated here
24
          Ω
                                                           24
25
          Α
                -- not there.
                                                                combined with, here, ethyl eicosapentaenoic --
                                               Page 171
                                                                                                          Page 173
 1
          Q
                And are you a formulator?
                                                                ethyl icosapent.
          Α
                I am not.
                                                            2
                                                                     BY MR. CLEMENT:
 3
                And you don't consider yourself an
                                                                           Okay. Just -- so you're saying that
     expert in formulation; right?
                                                                someone who is also on icosapent, if you were to
 5
          Α
                That is correct.
                                                                prescribe them a statin in addition to the
 6
                And in claim 1 there, right, I think
                                                                icosapent you would agree that is a concomitant
 7
     we -- I might have asked this already, but --
                                                                lipid-altering therapy; correct?
8
     well, strike that.
                                                                     Α
                                                                           Yes.
9
                Now, let's assume the pa- -- patient
                                                            9
                                                                           Do you know if the patent covers
    comes with you, right, at a triglyceride level of
                                                                methods for people not receiving diet and
10
     above 500 mgs per dl; right?
                                                                lifestyle change counseling?
11
                                                           11
12
          Α
                                                           12
                                                                           MR. KENNEDY: Objection to form.
13
                Let's -- let's take this back to
                                                           13
                                                                           THE WITNESS: Diet and lifestyle is --
          0
                                                                     BY MR. CLEMENT:
14
    2009 --
                                                           14
15
          Α
                Okay.
                                                           15
                                                                     0
                                                                           You know what -- let me --
          0
                -- okay?
16
                                                           16
                                                                     Α
                                                                           Yeah. Sorry.
17
                The first thing you're going to do is
                                                           17
                                                                     Q
                                                                            -- rephrase that. Okay. Let me strike
18
    say lifestyle changes; right?
                                                                that and rephrase.
                                                           18
19
          Α
                That is part and parcel of our
                                                           19
                                                                           Do you know if the patent claims
20
    discussion, ves.
                                                                methods for people -- patients not receiving diet
                                                           2.0
21
                And then if that doesn't take care of
                                                           21
                                                                and lifestyle change counseling?
    the problem, right, then you might prescribe also
                                                                           MR. KENNEDY: Objection to form.
22
                                                           22
23
    a medication; right?
                                                           23
                                                                           THE WITNESS: I would have to look
24
          Α
                Not necessarily.
                                                           24
                                                                at -- at the patents to see if that wording is
25
          0
                Not necessarily, okay.
                                                           25
                                                                used.
```

1					
	DA WD Cit inwinyan	Page 174		20000	Page 176
2	BY MR. CLEMENT:	l if would look to alaim	1	scope.	THE MITTIESS. I goo that and and
3	Q Okay. Wellet's say, 15 of the	1, if you'd look to claim,	2 3	and go t	THE WITNESS: I see that, and and
4	A I see it.	728.	4		the idea, again, is that you could a medication in patients who are coming
5		There it says the subject	5		atted triglyceride even if they are on a
6	_	ng a western diet; right?	6	western di	•
7		ods head.)	7		R. CLEMENT:
8	,	r're on a western can you	8	0	And that would be different than the
9	-	e do you have strike	9	~	patent or the MARINE study, right,
10	that.		10		here everybody was on the lifestyle
11	Do you agr	ree with me that's what that	11	counseling	
12	claim is saying?		12	-	MR. KENNEDY: Objection to form.
13	A Yes.		13		THE WITNESS: That is different than
14	Q Do you kno	w what a western diet is?	14	what was u	used in MARINE.
15	A I do.		15	BY MF	R. CLEMENT:
16	Q And what i	s a western diet?	16	Q	And right. Okay.
17	A The west -	-	17		And what's exam the example of the
18	MR. KENNEI	Y: Objection to form.	18	patent; ri	lght?
19	Sorry. Go	ahead.	19	A	Well
20	THE WITNES	S: A western diet is a diet	20		MR. KENNEDY: Same objection.
21	that is consumed in w	esternized societies that	21		THE WITNESS: Yeah, as listed in 15.
22	typically is unhealth	y because it contains a fair	22	BY MF	R. CLEMENT:
23	amount of unhealthy f	ats and perhaps other	23	Q	Okay.
24	processed foods with	an associated elevated risk	24		MR. CLEMENT: Now, I'm going to mark
25	of heart disease comp	ared to eastern diets which	25	the next e	exhibit which is going to be Miller 17
1	are generally healthi	Page 175 er.	1	18. And i	Page 177 it's a document with defendants Bates
2	-				
	BY MR. CLEMENT:		2	range 1021	l1 through 10225.
3		l the patent actually says	2 3	range 1021	11 through 10225. (Miller Deposition Exhibit 18 was
	Q Okay. And	the patent actually says s; right? If you turn to			
3	Q Okay. And	s; right? If you turn to	3		(Miller Deposition Exhibit 18 was
3 4	Q Okay. And what a western diet i	s; right? If you turn to 38, I guess it is.	3 4	marked for	(Miller Deposition Exhibit 18 was
3 4 5	Q Okay. And what a western diet i column 9, line 29 to A Yes, that	s; right? If you turn to 38, I guess it is.	3 4 5	marked for	(Miller Deposition Exhibit 18 was a identification and attached to the
3 4 5 6	Q Okay. And what a western diet i column 9, line 29 to A Yes, that	s; right? If you turn to 38, I guess it is. that	3 4 5 6	marked for transcript BY MF Q	(Miller Deposition Exhibit 18 was didentification and attached to the E.) R. CLEMENT:
3 4 5 6 7	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree	s; right? If you turn to 38, I guess it is. that	3 4 5 6 7	marked for transcript BY MF Q	(Miller Deposition Exhibit 18 was identification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know
3 4 5 6 7 8	Q Okay. And what a western diet is column 9, line 29 to A Yes, that Q You'd agree patent? A Yes.	s; right? If you turn to 38, I guess it is. that	3 4 5 6 7 8	marked for transcript BY MF Q if you've	(Miller Deposition Exhibit 18 was didentification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document?
3 4 5 6 7 8	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, so	s; right? If you turn to 38, I guess it is that ee with that definition in the	3 4 5 6 7 8	marked for transcript BY MF Q if you've A	(Miller Deposition Exhibit 18 was a identification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document? I have.
3 4 5 6 7 8 9	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agre patent? A Yes. Q And, so, s diet is not on lipid-	s; right? If you turn to 38, I guess it is that ee with that definition in the comeone who is consuming that	3 4 5 6 7 8 9	marked for transcript BY MF Q if you've A Q	(Miller Deposition Exhibit 18 was a identification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document? I have.
3 4 5 6 7 8 9 10	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, so diet is not on lipid- MR. KENNEL	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right?	3 4 5 6 7 8 9 10	marked for transcript BY MF Q if you've A Q on?	(Miller Deposition Exhibit 18 was definition and attached to the decomposition and detached to the decomposition and decomposition
3 4 5 6 7 8 9 10 11 12 13	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, se diet is not on lipid- MR. KENNEL MR. CLEMEN All right.	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right? Y: Objection.	3 4 5 6 7 8 9 10 11 12 13	marked for transcript BY MF Q if you've A Q on? A	(Miller Deposition Exhibit 18 was didentification and attached to the didentification and attached to the didentification and
3 4 5 6 7 8 9 10 11 12 13	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, so diet is not on lipid- MR. KENNEL MR. CLEMEN All right. BY MR. CLEMENT:	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right? Y: Objection. TT: I'm sorry. Thank you. Strike that.	3 4 5 6 7 8 9 10 11 12 13	marked for transcript BY MF Q if you've A Q on? A Q	(Miller Deposition Exhibit 18 was identification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document? I have. And this is one that you're an author I am. This was published in 2007?
3 4 5 6 7 8 9 10 11 12 13 14 15	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, so diet is not on lipid- MR. KENNEL MR. CLEMEN All right. BY MR. CLEMENT: Q And, so, t	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right? Y: Objection. TI: I'm sorry. Thank you. Strike that. the person on a western diet	3 4 5 6 7 8 9 10 11 12 13 14 15	marked for transcript	(Miller Deposition Exhibit 18 was identification and attached to the E.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document? I have. And this is one that you're an author I am. This was published in 2007? It was, yes. Okay. And it's with Terry Jacobson? Yes.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agre patent? A Yes. Q And, so, s diet is not on lipid- MR. KENNEL MR. CLEMEN All right. BY MR. CLEMENT: Q And, so, t is not, in your opini lifestyle counseling; A (Witness in	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right? Y: Objection. TI: I'm sorry. Thank you. Strike that. the person on a western diet on, receiving therapeutic right? reviews document.)	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	marked for transcript BY MF Q if you've A Q on? A Q A Q A Q A Q A Out of Atl	(Miller Deposition Exhibit 18 was didentification and attached to the didentification and attached to the didentification and didentification
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agree patent? A Yes. Q And, so, se diet is not on lipid- MR. KENNEI MR. CLEMEN All right. BY MR. CLEMENT: Q And, so, t is not, in your opini lifestyle counseling; A (Witness r The wester	s; right? If you turn to 38, I guess it is that e with that definition in the someone who is consuming that altering therapy; right? W: Objection. TI: I'm sorry. Thank you. Strike that. the person on a western diet on, receiving therapeutic right? Thereviews document.) The diet is not a diet that I	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	marked for transcript BY MF Q if you've A Q on? A Q A Q A Q A Q A Out of Atl	(Miller Deposition Exhibit 18 was a identification and attached to the c.) R. CLEMENT: And Dr. Miller, can you let me know ever seen this document? I have. And this is one that you're an author I am. This was published in 2007? It was, yes. Okay. And it's with Terry Jacobson? Yes. Who is Terry Jacobson? He is a colleague of mine who is based lanta. He is a cardiologist. Would he be a person of ordinary skill
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Okay. And what a western diet i column 9, line 29 to A Yes, that Q You'd agre patent? A Yes. Q And, so, s diet is not on lipid- MR. KENNEL MR. CLEMEN All right. BY MR. CLEMENT: Q And, so, t is not, in your opini lifestyle counseling; A (Witness n The wester would prescribe to my Q But it is	s; right? If you turn to 38, I guess it is that e with that definition in the comeone who is consuming that altering therapy; right? Y: Objection. TI: I'm sorry. Thank you. Strike that. The person on a western diet on, receiving therapeutic right? Teviews document.) The diet is not a diet that I Tepatients. The patients. The patients is received to the strike that I Tepatients. The patients is received to the strike that I Tepatients.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	marked for transcript BY MF Q if you've A Q on? A Q A Q A Q A Q A out of Atl	(Miller Deposition Exhibit 18 was deficited in and attached to the second in identification and it is one that you - let me know ever seen this document? I have. And this is one that you re an author I am. This was published in 2007? It was, yes. Okay. And it's with Terry Jacobson? Yes. Who is Terry Jacobson? He is a colleague of mine who is based lanta. He is a cardiologist. Would he be a person of ordinary skill Yes.
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		Page 178		,	Page 180
1	Q	What about Ernst Schaefer?	1	see chang	
2	A	Yeah, Ernie is based out of the Bo-the	2	111-	So the small scale studies may have not
3		ea, another	3	-	nown you a lot, but now when you put it
4	Q	And is he	4	_	er in a meta-analysis, it can drive one
5	A	physician another expert.	5	-	ne other the the thoughts or the
6	Q	Would you consider him a person of	6		s that were being generated.
7		skill in the art	7	Q	Okay. And on the very first page of
8	A	Yes.	8		cle of yours, you have a results section;
9	Q	at least a person of ordinary	9	right?	
10	skill		10	A	Yes.
11	A	Yes.	11	Q	And you say, Concern over the
12	Q	in the art as you defined?	12		g rate of hypertriglyceridemia; right?
13	A	Yes.	13		000 or above
14	Q	What about as an expert?	14	A	No.
15	A	He's an expert.	15	Q	mgs per dl?
16	Q	Okay. Is is this a review article?	16	A	Not necessarily.
17	A	Yes.	17	Q	No, no?
18	Q	And what does that mean, it's a review	18	A	It's not, let's say, very high
19	article?		19		rides. Hypertriglyceridemia can be
20	A	Basically reviews the substantive	20	defined a	s a triglyceride as low as 200.
21	informatio	on at the time as it relates to the topic	21	Q	But it could also include people above
22	being eval	uated.	22	500?	
23	Q	All right. And you don't do any	23	A	Not not in this context.
24	additional	clinical research; you're just looking	24	Q	Not in this context?
25	at what's	been published before?	25	A	No.
			_		
1	А	Page 179 Right. There there are no new or	1	Q	Page 181 Okay.
1 2		_	1 2	Q	
		Right. There there are no new or			Okay.
2	no new stu	Right. There there are no new or dies in here or no new original studies.	2	agents th	Okay. But they do talk about lipid-lowering
2 3	no new stu Q A	Right. There there are no new or dies in here or no new original studies. And what was this article about?	2 3	agents th	Okay. But they do talk about lipid-lowering hat could be used for
2 3 4	no new stu Q A	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to	2 3 4	agents th	Okay. But they do talk about lipid-lowering hat could be used for
2 3 4 5	no new stu Q A cardiovaso	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to cular disease and elevated triglycerides.	2 3 4 5	agents th	Okay. But they do talk about lipid-lowering wat could be used for glyceridemia, right, in this results
2 3 4 5 6	no new stu Q A cardiovaso	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand	2 3 4 5 6	agents th hypertrig section? A Q	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes.
2 3 4 5 6 7	no new stu Q A cardiovaso Q column, yo	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to cular disease and elevated triglycerides. And on page 764, the lower left hand ou talk about a meta-analysis; right?	2 3 4 5 6 7	agents the hypertrig section? A Q niacin, t	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates,
2 3 4 5 6 7 8	no new stu Q A cardiovasc Q column, yo	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand ou talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a	2 3 4 5 6 7 8	agents the hypertrig section? A Q niacin, t	Okay. But they do talk about lipid-lowering that could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, thiazolidinediones and prescription
2 3 4 5 6 7 8	no new stu Q A cardiovaso Q column, yo A Q	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand ou talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a	2 3 4 5 6 7 8	agents the hypertrig section? A Q niacin, to omega-3 f	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids?
2 3 4 5 6 7 8 9	no new stu Q A cardiovaso Q column, yo A Q meta-analy	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to cular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis?	2 3 4 5 6 7 8 9	agents the hypertrig section? A Q niacin, tomega-3 f	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle
2 3 4 5 6 7 8 9 10	no new stu Q A cardiovaso Q column, yo A Q meta-analy	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We	2 3 4 5 6 7 8 9 10	agents the hypertrig section? A Q niacin, to omega-3 f A Q	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle
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2 3 4 5 6 7 8 9 10 11 12	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We he data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define	2 3 4 5 6 7 8 9 10 11 12 13	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We he data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define	2 3 4 5 6 7 8 9 10 11 12 13 14	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results,	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these
2 3 4 5 6 7 8 9 10 11 12 13 14	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for u A	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand but talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We she data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define as?	2 3 4 5 6 7 8 9 10 11 12 13 14	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results,	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for u A designed t	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We he data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define as? Yeah. So meta-analysis is really to enhance the stature the recognition	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results,	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right? MR. KENNEDY: Objection to form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for u A designed t of a findi	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We he data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define his? Yeah. So meta-analysis is really no enhance the stature the recognition and that that now incorporates a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results,	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	no new stu Q A cardiovase Q column, ye A Q meta-analy A reviewed t Q that for u A designed t of a findi number of subjects.	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We he data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define is? Yeah. So meta-analysis is really to enhance the stature the recognition ing that that now incorporates a studies and a number of additional	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results, statins of the control of th	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right? MR. KENNEDY: Objection to form. THE WITNESS: Not in this paragraph, MR. CLEMENT: And on page 766, right, you talk about
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for t A designed t of a findi number of subjects.	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We she data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define as? Yeah. So meta-analysis is really so enhance the stature the recognition and that that now incorporates a studies and a number of additional For example, you could have several crials that may trend towards	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results, statins of the control of th	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right? MR. KENNEDY: Objection to form. THE WITNESS: Not in this paragraph,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for u A designed t of a findi number of subjects.	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand ou talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We she data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define as? Yeah. So meta-analysis is really so enhance the stature the recognition and that that now incorporates a studies and a number of additional For example, you could have several crials that may trend towards are, and now you and they are studying	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results, statins of the section of the section?	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right? MR. KENNEDY: Objection to form. THE WITNESS: Not in this paragraph, MR. CLEMENT: And on page 766, right, you talk about recommendations; right? Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	no new stu Q A cardiovaso Q column, yo A Q meta-analy A reviewed t Q that for u A designed t of a findi number of subjects. clinical t significar relatively	Right. There there are no new or dies in here or no new original studies. And what was this article about? Basically the issue as it relates to rular disease and elevated triglycerides. And on page 764, the lower left hand on talk about a meta-analysis; right? (Witness nods head.) Is that what was conducted here, a rsis? Well, not conducted for this. We she data that included meta-analysis. Meta-analysis, okay. And a "meta-analysis" can you define as? Yeah. So meta-analysis is really so enhance the stature the recognition and that that now incorporates a studies and a number of additional For example, you could have several crials that may trend towards	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	agents the hypertrig section? A Q niacin, to omega-3 f A Q changes; A Q results, statins of the state of the	Okay. But they do talk about lipid-lowering nat could be used for glyceridemia, right, in this results Yes. And that includes statins, fibrates, chiazolidinediones and prescription fatty acids? Yes. And it says, Along with lifestyle right? Yes. And you don't there's no in these there's no mention of any problems with or fibrates or niacin; right? MR. KENNEDY: Objection to form. THE WITNESS: Not in this paragraph, MR. CLEMENT: And on page 766, right, you talk about the recommendations; right?

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1	Page 182 of this publication you were trying to inform	1	Page 184 TG-lowering therapy, right, true then and true
2	doctors about; correct?	2	now?
3	A Yeah, we were just kind of summarizing	3	A Yeah.
4	the available information.	4	Q Okay. And that would include for
5	Q If you go to the next page, 767 where	5	severe hypertriglyceridemia in addition to hyp
6	you talk about triglyceride-lowering therapy,	6	just general hypertriglyceridemia; correct?
7	lifestyle modification?	7	MR. KENNEDY: Objection to form.
8	A Yes.	8	THE WITNESS: Yeah, severe
9	Q And you note there, right, that weight	9	hypertriglyceridemia is a is a a little
10	loss and exerc increased exercise are the	10	bit while we while we certainly recommend
11	cornerstones of TG-lowering therapy; right?	11	weight loss and increased exercise, more often
12	A As they are for blood pressure	12	than not we would need to highly consider the use
13	reduction, glucose reduction, weight loss, LDL	13	of a lipid or a triglyceride-lowering medication.
14	reduction, weight loss and increased exercise are	14	BY MR. CLEMENT:
15	the corner stones of all virtually all	15	Q In addition to the
16	therapies to reduce heart disease risk.	16	A Well
17	Q Okay.	17	Q diet and exercise regiment; right?
18	A So it's not unique to triglycerides.	18	A Diet and exercise is is exclusive to
19	It is a broad it's broad-based, and it is part	19	that. We we that that is broad-based.
20	and parcel of treatment for everybody. It is not	20	We recommend that to everybody. That is not what
21	specifically lipid-lowering therapy. I would not	21	I would refer to as lipid-lowering medication.
22	classify it as lipid-lowering therapy as I would	22	And, so, in patients who have very high
23	for ezetimibe, a lipid-lowering therapy	23	triglycerides, above 500, more often than not they
24	ezetimibe to lower LDL or statins to lower LDL or	24	will need to go on medication and diet. While we
25	fibrates to lower TG. So difference	25	would certainly want them to employ therapeutic
1	Page 183 Q Understood.	1	Page 185 lifestyle changes, more often than not they will
1 2		1 2	
	Q Understood.		lifestyle changes, more often than not they will
2	Q Understood. A But it is but it is it is the	2	lifestyle changes, more often than not they will also need medication.
2 3	Q Understood. A But it is but it is it is the cornerstone of all preventative types of	2 3	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next
2 3 4	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies.	2 3 4	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates;
2 3 4 5	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood.	2 3 4 5	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right?
2 3 4 5 6	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight	2 3 4 5 6	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes.
2 3 4 5 6 7	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones	2 3 4 5 6 7	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies;
2 3 4 5 6 7 8	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were	2 3 4 5 6 7 8	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations?
2 3 4 5 6 7 8	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride	2 3 4 5 6 7 8	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct.
2 3 4 5 6 7 8 9	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride lowering; right?	2 3 4 5 6 7 8 9	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct. Q Yeah.
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2 3 4 5 6 7 8 9 10 11 12	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride lowering; right? A Because it's a triglyceride paper. If this was an LDL paper, I would have said weight	2 3 4 5 6 7 8 9 10 11 12	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct. Q Yeah. And no mention of rhabdomyolysis here; right?
2 3 4 5 6 7 8 9 10 11 12 13	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride lowering; right? A Because it's a triglyceride paper. If this was an LDL paper, I would have said weight loss and increased exercise are the cornerstone of	2 3 4 5 6 7 8 9 10 11 12 13	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct. Q Yeah. And no mention of rhabdomyolysis here; right? A I would actually have to look at the
2 3 4 5 6 7 8 9 10 11 12 13	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride lowering; right? A Because it's a triglyceride paper. If this was an LDL paper, I would have said weight loss and increased exercise are the cornerstone of LDL-lowering Q Very A therapy.	2 3 4 5 6 7 8 9 10 11 12 13	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct. Q Yeah. And no mention of rhabdomyolysis here; right? A I would actually have to look at the rest of the article to see if it's in here, but
2 3 4 5 6 7 8 9 10 11 12 13 14	Q Understood. A But it is but it is it is the cornerstone of all preventative types of therapies. Q Understood. But here your sentence says, Weight loss and increased exercise are the cornerstones of TG-lowering therapy. So here you were specifically talking about T triglyceride lowering; right? A Because it's a triglyceride paper. If this was an LDL paper, I would have said weight loss and increased exercise are the cornerstone of LDL-lowering Q Very	2 3 4 5 6 7 8 9 10 11 12 13 14	lifestyle changes, more often than not they will also need medication. Q Okay. That's fair. Then on the next page you talk about on page 768, fibrates; right? A Yes. Q And these are recommended therapies; right treatment recommendations? A In 2009, that is correct. Q Yeah. And no mention of rhabdomyolysis here; right? A I would actually have to look at the rest of the article to see if it's in here, but not in that paragraph.
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		, 10	
Page 186	1	0	Page 188
Q Okay. But it also says on page 770,	1	Q	And you're listed as the chair?
right, in the paragraph 70 beginning, Gemfibrozil	2	A	Correct.
		~	Okay. And there's a Neil Stone also on
			W
			Yes.
		-	article
			Yes.
1			or statement, I should say.
			Yes.
		~	Who is Neil Stone?
- · · · · · · · · · · · · · · · · · · ·			Neil Stone is a professor at
-			ern who is also the chair of the national
		_	3 2013, American AHA/ACC.
			And would you consider him as a person
hence that has to be included in a review paper or		of ordinar	y skill in the art?
any other paper.	16	A	Yes.
-	17	Q	And as an expert?
medication, right, first do no harm. You don't	18	A	Yes.
want to you don't want to give them something	19	Q	How about Christie Ballantyne?
that could just be an allergic rela reaction	20	A	Christie Ballantyne is is in at
to one of the ingredients; right? You want to	21	Baylor in	Houston.
you don't want to do any harm. No question about	22	Q	And is she a
it that's a given.	23	A	It's a he.
But this says they're generally well	24	Q	It's a he. Sorry.
tolerated; right?	25		And is he a person
Davis 107			D 100
A Generally well tolerated, yeah, sure.	1	А	Yes. Page 189
MR. CLEMENT: All right. Why don't we	2	Q	you would consider a person of
break for lunch.	3	ordinary s	skill in the art?
THE VIDEOGRAPHER: The time is 12:29.	4	A	Yes.
This concludes tape number 3.	5	Q	And an expert?
(Recess 12:29 p.m.)	6	A	Yes.
(After recess 1:15 p.m.)	7	Q	And the same questions for Vera
THE VIDEOGRAPHER: The time is	8	Bittner?	
1:15 p.m. This begins tape number 4. We're on	9	A	Vera is over in Alabama, and, yes,
the record.	10	she's an e	expert.
Please proceed, Counsel.	11	Q	And at least a person of ordinary skill
			-
MR. CLEMENT: Okay. I will have the	12	in the art	as you've defined; right?
MR. CLEMENT: Okay. I will have the court reporter mark an AHA Scientific Statement	12 13	in the art	as you've defined; right? Correct.
•			
court reporter mark an AHA Scientific Statement	13	А	Correct.
court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19.	13 14	A Q	Correct. And how about Michael Criqui?
court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19. (Miller Deposition Exhibit 19 was	13 14 15	A Q A	Correct. And how about Michael Criqui?
court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19. (Miller Deposition Exhibit 19 was marked for identification and attached to the	13 14 15 16	A Q A also.	Correct. And how about Michael Criqui? Mike is in San Diego, and, yes, he is,
court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19. (Miller Deposition Exhibit 19 was marked for identification and attached to the transcript.)	13 14 15 16 17	A Q A also. Q	Correct. And how about Michael Criqui? Mike is in San Diego, and, yes, he is,
court reporter mark an AHA Scientific Statement article authored by Michael Miller, Exhibit 19. (Miller Deposition Exhibit 19 was marked for identification and attached to the transcript.) BY MR. CLEMENT:	13 14 15 16 17 18	A Q A also. Q the art?	Correct. And how about Michael Criqui? Mike is in San Diego, and, yes, he is, At least a person of ordinary skill in
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	Q That's that's true of any medication, right, first do no harm. You don't want to you don't want to give them something that could just be an allergic rela reaction to one of the ingredients; right? You want to you don't want to do any harm. No question about it that's a given. But this says they're generally well tolerated; right? Page 187 A Generally well tolerated, yeah, sure. MR. CLEMENT: All right. Why don't we break for lunch. THE VIDEOGRAPHER: The time is 12:29. This concludes tape number 3. (Recess 12:29 p.m.) (After recess 1:15 p.m.) THE VIDEOGRAPHER: The time is 1:15 p.m. This begins tape number 4. We're on	A Yes. Q And then it says, These agents are generally well tolerated; right? A Generally well tolerated, right, but it it doesn't take away from the concern as a physician the first thing we learn in medical school is "primum non nocere," first do no harm. So even though these medications and others are well tolerated, we always have to take into consideration the possibility of harm, and hence that has to be included in a review paper or any other paper. Q That's that's true of any medication, right, first do no harm. You don't want to you don't want to give them something that could just be an allergic rela reaction to one of the ingredients; right? You want to you don't want to do any harm. No question about it that's a given. But this says they're generally well tolerated; right? A Generally well tolerated, yeah, sure. MR. CLEMENT: All right. Why don't we break for lunch. THE VIDEOGRAPHER: The time is 12:29. This concludes tape number 3. (Recess 12:29 p.m.) (After recess 1:15 p.m.) THE VIDEOGRAPHER: The time is 8 1:15 p.m. This begins tape number 4. We're on	fibrates in the U.S.; right? A Yes. Q And then it says, These agents are generally well tolerated; right? A Generally well tolerated, right, but it it doesn't take away from the concern as a physician the first thing we learn in medical school is "primum non nocere," first do no harm. So even though these medications and others are well tolerated, we always have to take into consideration the possibility of harm, and hence that has to be included in a review paper or any other paper. Q That's that's true of any medication, right, first do no harm. You don't want to you don't want to give them something that could just be an allergic rela reaction to one of the ingredients; right? You want to you don't want to do any harm. No question about it that's a given. But this says they're generally well tolerated; right? A Generally well tolerated, yeah, sure. MR. CLEMENT: All right. Why don't we break for lunch. THE VIDEOGRAPHER: The time is 12:29. This concludes tape number 3. (Recess 12:29 p.m.) (After recess 1:15 p.m.) THE VIDEOGRAPHER: The time is 8 Bittner? 1:15 p.m. This begins tape number 4. We're on 9 A

1	where my	Page 190 daughters go next year. And	1	Page 192 document, the excerpts. No? It should start
2	Q Q	Congratulations.	2	with yeah, it starts with the Bays declaration
3	A	Thank you.	3	exactly. Yeah.
4		And, yes, she is an expert.	4	MR. KENNEDY: Yeah. Then I think
5	Q	What about William James?	5	that's the
6	A	Bill Howard, he's in Wa he's in	6	MR. CLEMENT: That's the cover page of
7		He may be retired now, but he was	7	16.
8	-	an expert.	8	BY MR. CLEMENT:
9	0	And Marc Jacobson, he was on the	9	Q Okay. If you can turn to 3058248,
10	~	ith you before?	10	towards the beginning. Do you have that page?
11	A	That was Terry.	11	A I do.
12	Q	Terry, okay.	12	Q Okay. And this was something you
13	a A	But Marc and Kris and Terry and Moshe	13	relied on, right, in your declaration?
14		re Subramanian would all be viewed as	14	A Yes.
15	experts.		15	Q And this is a this was attached to
16	0	So Terry Lennie would be viewed as a	16	the Bays declaration; is that true?
17	~	ordinary skill?	17	A I believe so.
18	A	Yes.	18	Q Yeah.
19	Q	And same as Moshe Levi?	19	And what's on this page, 8248? Is
20	A	Yes.	20	that, like, the description of the study?
21	Q	Same as Theodore Mazzone?	21	A Yes, it's the introduction methods and
22	A	Ted Mazzone, yes.	22	study design.
23	Q	And also Subramanian Pennathur?	23	Q And that should be match up with the
24	A	Subramanian, yes.	24	study in the patent?
25	Q	All right. And this article is dated	25	MR. KENNEDY: Objection to form.
		5		
1	2011. rigi	Page 191	1	Page 193
1 2	2011; rig	nt?	1 2	THE WITNESS: It should be reasonably
2	A	Yes.	2	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid
2 3		Yes. Okay. You can put that away.	2 3	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria
2 3 4	A Q	Yes. Okay. You can put that away. In your review of the patent, the '728	2 3 4	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT:
2 3 4 5	A Q patent	Yes. Okay. You can put that away. In your review of the patent, the '728 let's stick with that one did that	2 3 4 5	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT: Q Okay.
2 3 4 5 6	A Q patent describe	Yes. Okay. You can put that away. In your review of the patent, the '728 let's stick with that one did that a completed study or a just the	2 3 4 5 6	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT: Q Okay. A and medications that patients were
2 3 4 5 6 7	A Q patent describe protocol:	Yes. Okay. You can put that away. In your review of the patent, the '728 let's stick with that one did that a completed study or a just the for a study?	2 3 4 5 6 7	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT: Q Okay. A and medications that patients were taking.
2 3 4 5 6 7 8	A Q patentdescribe protocol:	Yes. Okay. You can put that away. In your review of the patent, the '728 let's stick with that one did that a completed study or a just the for a study? Well, it's it's a a protocol for	2 3 4 5 6 7 8	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT: Q Okay. A and medications that patients were taking. Q Okay. You agree this was a
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2 3 4 5 6 7 8	patent describe a protocol: A a study, a at the time	Yes. Okay. You can put that away. In your review of the patent, the '728 let's stick with that one did that a completed study or a just the for a study? Well, it's it's a a protocol for and I don't know where that study stood me of the filing, but ultimately it	2 3 4 5 6 7 8	THE WITNESS: It should be reasonably close certainly from the standpoint of lipid eligibility criteria BY MR. CLEMENT: Q Okay. A and medications that patients were taking. Q Okay. You agree this was a double-blind study; right? A Yes.
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24 Q Right. What were the secondary 24 use a significance level of p as .05?				
		2 5	1	J
		endpoints?	25	MR. KENNEDY: Objection to form.

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Page 198
                                                                                                          Page 200
 1
                THE WITNESS: Yeah, again, I'm not a
                                                               on, it says, Assuming a standard deviation of
 2
     statistician, so I don't know. And I was not
                                                               45 percent TG measurements and a significance
 3
     involved in the MARINE trial, so --
                                                               level of less than .01.
         BY MR. CLEMENT:
 4
                                                           4
                                                                           So those who are consistent.
 5
                So sitting here today, you can't point
                                                                           Right. I agree. That's the primary
     to anything in the patent showing that the
                                                               variable. I'm asking about the secondary which is
 7
     statistical significance level for the secondary
                                                               the LDL and the ApoB; right?
8
     endpoints should be .05; right?
                                                                           I -- I don't see it in the '728. It
9
                MR. KENNEDY: Objection to form.
                                                               doesn't rule out the possibility that it may exist
10
                THE WITNESS: Actually, I don't know if
                                                                in one of the other asserted patents.
     that's true because I would need to go through in
                                                                           Okay. But you don't see it here in the
11
                                                                     Q
     fine detail the prosecution history where that
                                                                '728; right?
12
                                                           12
     information may reside, and I could also go
                                                                           I haven't -- I didn't see it when I
13
                                                           13
                                                                     Α
     through the specification to --
14
                                                               just glanced over it.
         BY MR. CLEMENT:
                                                           15
15
                                                                     Q
                                                                           Okay. What is the NCEP therapeutic
16
                That's fair.
                                                          16
                                                               lifestyles changes diet?
17
                -- see if it's there.
                                                           17
                                                                           So a therapeutic lifestyle diet is --
18
                But I'd like you to look through the
                                                          18
                                                               is really a diet that incorporates lower amount
19
     specification. I don't think we need to look
                                                           19
                                                               of -- of fat in the diet, usually a reduction in
20
     through the prosecution history right now. I'd
                                                               total unsaturated fat, maintaining macro nutrient
21
     like you to look at the specification.
                                                           21
                                                               composition in a manner that may be reflective for
22
                (Witness reviews document.)
                                                          22
                                                               allowing a subject to reduce his or her weight.
23
                So with respect to the specification, I
                                                          23
                                                                           I mean, they're general -- they're
    don't see -- I -- I can't answer your specific
                                                               general recommendations.
24
                                                          24
25
    question, but that doesn't preclude the
                                                           25
                                                                    0
                                                                           I guess -- yeah. So what -- do you --
                                               Page 199
                                                                                                          Page 201
    possibility that that information resides in the
                                                               do you have the NCEP -- third report of the NCEP
    prosecution -- elsewhere in the prosecution
                                                               panel there which would have been Miller 15?
 3
    history.
                                                                           I have it right here.
          Q
                But it's not in the patent
                                                                           Okay. If you turn to 290029, and I
     specification; right?
                                                               just want to know if that's kind of what you're
5
 6
                I -- I do not see it.
                                                               talking about with regard to what the TLC would
 7
                And both change in --
                                                               be?
 8
                Oh, one second. Hold -- hold -- hold
                                                                    Α
                                                                           So 290029?
9
     on one second. Sorry.
                                                                     0
10
                Your question related to .05 and .01;
                                                                           Essential components of a therapeutic
     is that right?
11
                                                               lifestyle change, so the recommendation is to
                                                               reduce saturated fat, reduce dietary cholesterol,
12
13
                So .05 is under column 16 starting at
                                                          13
                                                               adjust total caloric intake for -- either to
14
    line 31 where they said, The least square means,
                                                          14
                                                               maintain body weight or perhaps to lose some,
15
     standard error and two-tailed 95 percent
                                                          15
                                                               physical activity.
    confidence interval for each treatment.
                                                                           Right. So what's described in Tables
16
                                                          16
17
                And then going to line 47 when they're
                                                          17
                                                               1, 2 and 3 on that page, would that be your
18
    talking about the sample size number needed to
                                                          18
                                                               understanding of --
19
     identify a difference with a significance level
                                                          19
                                                                     Α
                                                                           So that would be -- so that's -- Table
20
    of -- as less than .01.
                                                          20
                                                               1 is essential components, Table 2 is
21
                That's not .05; right?
                                                          21
                                                               macronutrient recommendations and Table 3 is --
                                                               I'm not sure about Table 3. I mean, it's dietary
22
                The statistical analysis in -- on
                                                          22
23
    page 8249 says, The primary efficacy analysis was
                                                          23
                                                               quidelines for Americans.
24
    performed using a Wilcoxon rank-sum test at a
                                                          24
                                                                     Q
                                                                           Okay. So 1 and 2?
                                                           25
25
    significance of 0.01. And if we look at line 45
                                                                    Δ
                                                                           One and 2 I think are --
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	<u> </u>		
	Page 202		Page 204
1	Q Okay.	1	the results; right?
2	A reasonable.	2	MR. KENNEDY: Objection to form.
3	Q That's good. Okay.	3	THE WITNESS: Well, in any clinical
4	Now, in the study protocol for the	4	trial if you go off your medications or you do
5	example in the patent, right, the '728 patent,	5	things you're not you shouldn't be doing, then
6	remember the example?	6	of course it could skew it might skew your
7	A Yes.	7	results.
8	Q When were the baseline triglyceride	8	BY MR. CLEMENT:
9	measurements taken?	9	Q Now, in the protocol were the subjects
10	A Yes, I I believe the blood levels,	10	allowed to the subjects who strike that.
11	if I'm not mistaken, were taken after this four-	11	In in the protocol in the example
12	to six-week washout period. And then there was an	12	in the patent, were subjects allowed if they
13	average. You could have one drawn after the four-	13	were taking a statin, were they allowed to
14	to six-week period and then you could then you	14	continue taking a statin?
15	would repeat that, I believe, within a week or	15	A That was my recollection, is that they
16	two; take the average of those two and then	16	could be on a statin a percentage of those
17	determine eligibility with the possibility that if	17	patients, maybe 25 percent, were taking a statin,
18	that person's triglyceride was outside that range	18	and they could remain on a statin.
19	but in the ballpark, you may do a third one and	19	The only medications they could not
20	then take the average of the third one and the	20	remain on other medications, but they could remain
21	second one. Typic the typical way that	21	on a statin they I mean, I think ezetimibe
22	clinical trials are conducted.	22	might have been permitted. But they couldn't
23	Q Okay. And once you got that number,	23	remain on medication that might affect
24	that was your baseline; right?	24	triglycerides.
25	A That would be that would determine	25	Q That was one another one of my
1	Page 203 actual eligibility to participate in the clinical	1	Page 205 questions. I can't I don't remember if I
2	trial.	2	remember clearly. Was ezetimibe allowed to be
3	Q And if you were eligible to participate	3	continued?
4	in the clinical trial, that would represent the	4	A I'll have to look. Let me Let me
5	baseline for that subject?	5	check.
6	A That would represent the baseline for	6	Q Go ahead and take a look. Sure.
7	that subject.	7	A Because I again, I was not a part of
8	Q Okay. Now, it is true that subjects	8	the study but if recollection serves me correctly,
9	A For the for the purposes of the	9	that was the case.
10	of the clinical trial.	10	MR. KENNEDY: Do you need the patent?
11	Q Of the clinical trial?	11	THE WITNESS: No, I'm looking actually
12	A Of the clinical trial.	12	for the clinical trial.
13	Q Right.	13	MR. KENNEDY: Oh, I think it is one of
14	So the subject could then change his	14	the big big guys.
15	diet or no?	15	THE WITNESS: One of the big guys?
16	A No, the diet was recommended throughout	16	BY MR. CLEMENT:
17	the study	17	Q I think it's in one of the file
18	Q But if they	18	histories. If you want to look at that that
19	A as as is generally done.	19	document we were just looking at, it's in Miller
20	Now, whether or not a patient veers off	20	16.
21	his or her diet is a different issue, but the idea	21	MR. KENNEDY: The Bates
22	is for patients to maintain that that lifestyle	22	THE WITNESS: Oh, there it is.
23	that they were moni following. Q But if they were to change their diet	23	MR. KENNEDY: There you go.
25	or exercise, either more or less, that could skew	25	THE WITNESS: Great. What page was that?
45	of cactorse, etchet more of tess, that could skew	23	ciac:

	02/15		
	Page 206		Page 208
1	BY MR. CLEMENT:	1	at the column of 13 about line 63, it says, If
2	Q I think it's on	2	statin therapy (with or without ezetimibe) is to
3	A Okay. I got that.	3	be continued, dose must be stable for four weeks.
4	Q 248.	4	Does that mean if they were already on
5	Feel free to look it up, whatever you	5	ezetimibe in addition to the statin, they were
6	think you need to.	6	allowed to continue?
7	A (Witness reviews document.)	7	A Yes, that that that was my
8	So inclusion let's see. If on	8	understanding.
9	backgrounds statin therapy no change to statin	9	Q Okay. And ezetimibe is not a statin;
10	type or dose during the study was allowed.	10	right?
11	With respect to ezetimibe, I would	11	A That is correct.
12	actually have to look at the paper because I don't	12	Q But it is when taken in combination
13	see it here.	13	with icosapent and a statin, ezetimibe would also
14	Q But statins, they were allowed to	14	be considered a concomitant lipid-altering
15	continue on; right?	15	therapy?
16	A Yes, correct.	16	A Yes.
17	Q With icosapent and the statin, the	17	Q Is there any statistical-significance
18	statin would be considered concomitant	18	testing for subjects who are on statin therapy
19	lipid-altering therapy; right?	19	versus as opposed to subjects who are not?
20	A Yes.	20	They didn't break that out; right?
21	Q Does the patent say how many patients	21	MR. KENNEDY: Objection to form.
22	were on the statins?	22	BY MR. CLEMENT:
23	A Again, I would have to look through the	23	Q Do you follow my question, or am I
24	information presented both in specification and	24	A I understand
25	prosecution history.	25	Q being unclear?
	D 00F		D 000
_	Page 207		Page 209
1	Q Well	1	
2	Q Well A My I I think I would I believe		-
	A My I I think I would I believe	1	A your question.
2	A My I I think I would I believe that it would be in prosecution history if it	1 2	A your question. I I again, I know there were
2 3	A My I I think I would I believe	1 2 3	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received
2 3 4	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but	1 2 3 4	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better
2 3 4 5	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just	1 2 3 4 5	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received
2 3 4 5 6	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but	1 2 3 4 5 6	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin.
2 3 4 5 6 7 8	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what	1 2 3 4 5 6 7	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a
2 3 4 5 6 7	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself.	1 2 3 4 5 6 7 8	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin.
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2 3 4 5 6 7 8 9 10	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin?	1 2 3 4 5 6 7 8	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects?
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2 3 4 5 6 7 8 9 10 11 12 13 14	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is	1 2 3 4 5 6 7 8 9 10 11 12 13 14	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is specifically '728.	1 2 3 4 5 6 7 8 9 10 11 12 13 14	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall. Q Okay. Let's take a look at
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is specifically '728. Q Yeah.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall. Q Okay. Let's take a look at paragraph 40 of your opening declaration which is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is specifically '728. Q Yeah. A (Witness reviews document.)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall. Q Okay. Let's take a look at paragraph 40 of your opening declaration which is Miller 2.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is specifically '728. Q Yeah. A (Witness reviews document.) I I do not see reference to	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall. Q Okay. Let's take a look at paragraph 40 of your opening declaration which is Miller 2. Okay. At the end of that paragraph
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A My I I think I would I believe that it would be in prosecution history if it wasn't present in specification. Q Okay. Maybe in the pros I'm but my question is in the patent itself. I'm just asking in the patent itself. Is there a recitation of what percentage of patient of subjects of the study were on a statin? A I'll probably have to look through that. Q And just so you know A And, again sorry. And this is specifically '728. Q Yeah. A (Witness reviews document.) I I do not see reference to Q I I didn't A the percentage Q see it either. A of patients.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A your question. I I again, I know there were differences in the triglyceride reduction such that those volunteers in the trial who received both statin and icosapent appear to have better reduction in triglycerides than those who were on icosapent in the absence of statin. Q Okay. But do you know if there was a difference in the statistical-significance testing for those for those two different types of subjects? A We'd have to look through it. Q It's not mentioned in patent; right? A I don't recall. Q Okay. Let's take a look at paragraph 40 of your opening declaration which is Miller 2. Okay. At the end of that paragraph and feel free to read the entire paragraph, but you say, The clinical trial demonstrated that the invented method has numerous, unexpected and beneficial effects on lipid profiles in patients

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Page 210
                                                                                                          Page 212
 1
                So would you -- I quess, did you base
                                                                           MR. CLEMENT: Yeah, that's fair, but
 2
     that on the claim of the patent?
                                                               let's stop coaching the witness, too.
 3
                MR. KENNEDY: Objection to form.
                                                           3
                                                                           MR. KENNEDY: Okay.
         BY MR. CLEMENT:
                                                                     BY MR. CLEMENT:
 4
                                                           4
 5
                What the invented method was?
                                                           5
                                                                           So, again, it's really -- what
 6
                MR. KENNEDY: Objection to form.
                                                               happens -- the lipid levels, right, that -- that
 7
                THE WITNESS: I based that on the
                                                               are developed in the patient's bloodstream; right?
8
     totality of the infor- -- information that I had
                                                               Because that's what they do, they take the blood,
9
     available to me.
                                                               and then they run it through some sort of assay or
10
         BY MR. CLEMENT:
                                                           10
                                                               some analysis. And they can measure for
                Okay. And this invented method, right,
                                                               triglycerides, let's say, milligrams per
11
     that was -- included giving -- administering the
                                                               deciliter; right?
12
                                                           12
     4 grams of purified icosapent?
13
                                                           13
                                                                     Α
                                                                           That -- those numbers that come out of
14
                                                           14
                Did they take -- did the patients or
                                                               the blood or -- or get -- when they're analyzed,
15
                                                           15
16
     the subjects take anything else?
                                                               that's because of just when the patient ingests
17
                MR. KENNEDY: Objection to form.
                                                           17
                                                                the product, the body just metabolizes it however
18
                THE WITNESS: Well, if they may have
                                                          18
                                                               the body metabolizes it; right?
19
     also been taking their statin therapy and/or
                                                          19
                                                                           MR. KENNEDY: Objection to form.
20
    ezetimibe.
                                                          2.0
                                                                           THE WITNESS: Well, it's a little
21
         BY MR. CLEMENT:
                                                           21
                                                               bit -- that -- it's more than -- that's an
22
                Okay. And then their lipid parameters,
                                                          22
                                                               oversimplification.
23
    right, those -- that were talking about
                                                           23
                                                                           So after the instruction --
     triglycerides -- talking about triglycerides and
                                                               instructions are given with regard to
24
                                                           24
25
    ApoB for purposes of -- and LDL-C --
                                                               administration and the patient takes the
                                               Page 211
                                                                                                          Page 213
 1
                Yes.
                                                               medication, then that medication is absorbed and
          Q
                -- okay. Those were measured; right?
                                                               catabolized to some degree, and there are
 3
                Measured or calculated, correct.
                                                               different kinetic parameters involved in the
 4
                Okay. And those lipid levels, right,
                                                               bioavailability of the medication.
     that the -- were measured or calculated from the
                                                                     BY MR. CLEMENT:
 5
 6
     patient -- from the subject's bloods, those were
                                                                           That's all natural processes occurring
 7
     the natural result of a patient ingesting the
                                                               withinside the body. That's how the body acts on
8
     medication?
                                                               the medication.
9
                                                           9
                MR. KENNEDY: Objection to form;
                                                                           MR. KENNEDY: Objection to form.
                                                                           THE WITNESS: That's how ultimately it
10
    outside the scope.
                THE WITNESS: Yeah, I -- I think it was
11
                                                          11
                                                               gets processed.
                                                                     BY MR. CLEMENT:
12
    basically a by-product of having the physician
                                                          12
13
     recommending that the patient take the medication,
                                                          13
                                                                           Yeah.
14
     telling the patient what time he or she should
                                                                           And that would include for the ApoB
15
     take the medication, and then ultimately as part
                                                           15
                                                               levels, the LDL-C levels and the triglyceride
    of this process the patient taking the medication.
                                                               levels; right?
16
                                                          16
17
                MR. KENNEDY: By -- by the way just
                                                          17
                                                                           MR. KENNEDY: Objection to form.
18
    so -- so the record's clear, I think you've
                                                          18
                                                                           THE WITNESS: For all those blood
19
    developed a habit of saying yeah before a lot of
                                                          19
                                                               levels that were being evaluated, they would be --
20
    your answers. I don't know if that's intended or
                                                          20
                                                               blood sampling would be taken after a period of
21
    not, but in context sometimes yeah doesn't make
                                                          21
                                                               time that the patient had been exposed to either
                                                               the active compound or the inactive compound.
22
    any sense.
                                                          22
23
                THE WITNESS: Okay.
                                                           23
                                                                     BY MR. CLEMENT:
24
                MR. KENNEDY: So if you could just be
                                                                           And that -- you know, there would be a
                                                          24
    precise, and --
25
                                                               protocol for that; right? What time do you draw
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Page 214 Page 216 the blood; right? There's all sorts of protocols that's all natural processes; right? 2 that have to be taken within plus or minus five MR. KENNEDY: Objection to form. 3 minutes of certain times, right, spelled out in THE WITNESS: May or may not be natural the protocol? 4 because, again, we'd like to believe that it's 5 Α I think that might be a little 5 natural, but there could be some other -specific. I'm not sure that a patient had to have BY MR. CLEMENT: 7 his or her blood drawn at a specified time period. But --8 Uh-huh. 8 Α -- you know, intervening circumstance. 9 It's usually when a patient comes in 9 But you would agree it's all how the 10 for his or her follow-up visit, that designated body is acting on the drug after it's been time. There -- there is a window when you would ingested; right? 11 11 want that patient to come back, and that's 12 12 Α For the most part. specified in the protocol. 13 13 0 Yeah. 14 Okay. And, again, the -- the resulting 14 Well, what part wouldn't be? ApoB levels in the blood is just from the patient, 15 Α Well, you know, how one person responds 16 you know, taking the medication as prescribed, and to a medication could be different than another 17 it's just what comes out of the blood at that --17 person. 18 after that point; right? There's nothing -- no 18 Right. But that would be by their own 0 19 intervening act after the patient ingests the 19 inherent body makeup; right? 20 medication other than natural processes in the 20 It's just -- I -- I think with -- when 21 body that give you that ApoB level or that LDL-C 21 we view metabolism, it's -- it's a little bit more 22 22 complex, but I think the point you're suggesting level; right? 23 MR. KENNEDY: Objection to form. 23 is -- is -- is fairly reasonable. THE WITNESS: Yeah, I'm not -- I'm not 24 24 Okay. Okay. What does the word 0 25 quite sure if -- if it's as simple as that because "concurrent" mean? Page 215 Page 217 it's not as if you're taking or drinking a Α Concurrent is usually with -- with 1 milkshake and then determining the number of something else. 3 chylomicrons. So to see effects on a given And what about "concomitant"? parameter, it doesn't happen instantaneously. Α I view them very similarly. to see lipid effects, we're looking at a period of Okay. They're kind of synonymous; Q 6 time where those changes are observed, so -right? 7 BY MR. CLEMENT: 7 I think so. Α 8 And I'm not suggesting it happens Q Will exercise alter lipid levels? instantaneously. I agree with you. It takes MR. KENNEDY: Objection to form. 9 9 time. But everything that time is is things that THE WITNESS: Exercise might have an 10 the body is naturally doing in its course of effect on lipids as it would on blood pressure and 11 weight and glucose. So, yes, exercise is another 12 absorption, metabolism, distribution and 13 elimination; right? 13 broad-based measure that could -- that could 14 But, again, I want to point out that affect a lot of things. 15 the process of administration is a broad term. 15 BY MR. CLEMENT: It's not limited to somebody putting a pill in his And diet can also alter lipid levels; 16 16 0 17 or her mouth and then monitoring the blood levels. 17 right? 18 Right. I'm not going there. 18 As it could blood pressure and weight Α 19 I'm just saying after they take the 19 and glucose and so forth. 20 pill -- I'm not using the word "administering" at 20 All right. But lipid levels included; Q 21 all. Okay. 21 right? 22 After the person takes the pill when 22 Α It could affect lipids. It's not a 23 you then later at some point in time take the 23 lipid-lowering therapy, but it can affect lipids. blood sample, okay, to measure their ApoB levels Okay. If you turn to paragraph 53 in 24 24

your declaration. And here you're talking about

25

or LDL-Cs according to whatever the protocol is,

Page 218 Page 220 1 concomitant and concurrent lipid-altering therapy; 1 declaration. 2 right? So -- so you're relying on this portion 3 Α Yes. just to support your understanding of the term, not necessarily as a definition; right? 4 And you say they're understood in the 5 field to refer to other medications that a patient 5 Α Correct. may be taking that will overlap with a prescribed 0 Okay. Because "embodiment," that just 7 course of treatment; right? means it's giving an example; right? Yes. 8 Yes. 8 Α Α 9 What do you mean by "overlap"? 9 And even when it lists the medicaments, 10 Well, as I've stated earlier, lifestyle 10 right, it says, For example; correct? therapy or -- or therapeutic lifestyle change as Α I'm sorry. Where are you? 11 11 it is often referred to really is an initial So where it says, Statin, fibrate, 12 12 Q recommendation for all patients that are niacin and/or ezetimibe therapy. Do you see that? 13 13 14 presenting with any level of cardiovascular risk. Α So in this particular case here for 15 15 Q It's prefaced by that. The language is 16 patients that have -- or may need to be treated prefaced by "for example"; right? Do you see because of an abnormal lipid or an abnormal blood 17 17 that? 18 pressure or abnormal glucose, then we would make 18 Right. They could have included bile 19 recommendations for lifestyle therapy. acid sequestrants as well, and they didn't. 19 20 And then on paragraph 55 of your 20 They could have included a lot of 0 21 declaration, where you rely on -- you talk, again, 21 things. They just gave examples; right? 22 more about concomitant and concurrent 22 Well, no, this is medicine. This is Α 23 lipid-altering therapies; right? 23 clear as day to me that this refers specifically Α to medication. These are all medicines. I have 24 Yes. 24 25 0 And you rely on the patent, right, no reason to believe that it is anything Page 219 Page 221 here, column 12, lines 43 to 46 of the '728? otherwise. 2 I believe that's in the specification. Q Understood. 3 Okay. And if you turn to that, I mean, But they're just giving examples; would you consider that to be -- I mean, we talked rights? 5 earlier about definitions, right, that a Α Yes. 6 specification gives; right? And statin -- some of the people in the 7 Α example were on statins; right? 8 Is this definitional, do you think? Α As part of this clinical trial, the 9 MR. KENNEDY: Objection to form. MARINE clinical trial, yes. 9 10 THE WITNESS: Well, from the standpoint So if someone is on statins at the same 10 of this particular patent, it appears to be time they're on the icosapent and the claim says 11 11 medication. Lipid-altering therapy, I would -- I 12 not otherwise on lipid-altering therapies, they're 13 would view as lipid-altering medication given the 13 outside the scope of that; right? 14 examples of statin, fibrate, niacin and/or 14 MR. KENNEDY: Objection to form. 15 ezetimibe all of which are medications. 15 THE WITNESS: All right. Could you BY MR. CLEMENT: point to me where that is --16 16 BY MR. CLEMENT: 17 Okay. But this is not defining --17 do -- do you think this is defining the term 18 0 Look at --18 19 "lipid-altering therapy" -- I'm sorry. Strike 19 Α -- specifically --20 20 0 -- claim 1 --21 Do you think this portion of the '728 21 Α -- said. patent, column 12, lines 43 to 46, is defining the 22 22 0 -- and it says, A method of reducing 23 term "concomitant lipid-altering therapy"? 23 triglycerides in a subject having a fasting 24 I'm not sure this specific one is, but 24 baseline triglyceride level of 500 mgs to dl to

about 1500 mgs per dl who does not receive

there are others that I refer to in my

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Page 222
                                                                                                          Page 224
 1
     concomitant lipid-altering therapy; right?
                                                               it's your position, it's your opinion that statins
 2
                                                                although when taken with icosapent in general are
                So if they're on a statin, they're not
 3
     included on that claim, right, because they're on
                                                               a concomitant lipid-altering therapy.
                                                                           When you look at it in the context of
     a concomitant lipid-altering therapy under your
 4
                                                           4
5
     definition; right?
                                                           5
                                                               this claim, it's not? Is that what you're telling
 6
                Yes, so my -- my -- my understanding of
                                                               me?
 7
     concomitant lipid-altering therapy are those
                                                           7
                                                                           I'm not saying it's not. But what --
8
     individuals who may have been receiving niacin,
                                                               what I'm saying is when I'm looking at concurrent
9
     fibrates or other triglyceride-lowering
                                                               lipid-lowering medications, I'm thinking more in
10
     medications.
                                                               terms of the specific triglyceride-lowering
11
         0
                So --
                                                           11
                                                               medications.
12
                That was -- that was my understanding.
                                                          12
                                                                           The patent says in the section you
                                                               pointed to, column 3, lines 43 -- column 12, lines
13
                But the patent says otherwise. It
                                                          13
14
     says, For example, statins and ezetimibe; right?
                                                               43 to 46, all right, not otherwise -- that in
15
                Statins and ezetimibe were permitted as
                                                               accordance with the methods of the invention, not
16
    part of the MARINE trial.
                                                               otherwise on lipid-altering therapy, for
17
                Are they permitted as part of this
                                                           17
                                                               example -- the first one is statin.
18
    claim if it says they do not receive concurrent
                                                          18
                                                                           Now you're telling me that doesn't
19
     lipid-altering therapy?
                                                          19
                                                               count? Is that your testimony?
20
                MR. KENNEDY: Objection to form.
                                                          20
                                                                           Well, statins count. What I'm
21
                THE WITNESS: Well, I think it would
                                                          21
                                                               specifically referring to are
22
    have to be linked to the prosecution history where
                                                          22
                                                               triglyceride-lowering medications.
                                                                           Well --
23
     in the prosecution history it does establish that
                                                           23
                                                                     0
    the MARINE trial consisted of patients who
                                                                     Α
                                                                           Statins -- statins count. I think --
24
                                                          24
25
    received eicosapentaenoic and may also have
                                                               what my understanding here is lipid --
                                               Page 223
                                                                                                          Page 225
 1
     received statin --
                                                               lipid-altering therapy or medications that lower
 2
          BY MR. CLEMENT:
                                                               lipids -- medications that lower lipids, and
 3
                Is it possible --
                                                               that -- and that is how --
 4
                -- or ezetimibe.
                                                                     Q
                                                                           Well, statins lower lipids; right?
 5
                -- the MARINE -- is it possible the
                                                                    Α
                                                                           Yes, the --
 6
    MARINE trial -- the patients on that -- the
                                                                     0
 7
     statins and the ezetimibe in the MARINE trial just
                                                                     Α
                                                                           -- primary treatment for the use of
8
     aren't included in this claim?
                                                               statins is to lower LDL.
9
                MR. KENNEDY: Objection to form.
                                                           9
                                                                     0
                                                                           Which is a lipid?
10
                THE WITNESS: Oh, I -- I -- I
                                                           10
                                                                    Α
                                                                           Yes.
    wouldn't interpret it that way.
                                                                           And they're talking here -- they don't
11
                                                           11
          BY MR. CLEMENT:
                                                               say in the claim triglyceride-lowering concomitant
12
                                                           12
13
                Well, you've agreed with me before,
                                                           13
                                                               therapies, they say concomitant lipid-altering
14
    right, that statins are a concomitant
                                                          14
                                                               therapy which would include LDL?
15
    lipid-altering therapy; right?
                                                          15
                                                                           But I think they -- the point here is
16
                They are a concomitant lipid-altering
                                                               that the focus is on the hyper -- the very high
                                                          16
17
     therapy, but they are not a specific agent to
                                                           17
                                                               triglyceride patient, VHTG baseline triglyceride
18
    lower triglycerides.
                                                          18
                                                               of at least 500. And, so, when you're thinking of
19
                And this specific claim is to have
                                                           19
                                                               patients in the -- in the trial -- in the MARINE
20
    patients who have elevated -- very high
                                                               study with a fasting baseline triglyceride of 500,
21
    triglycerides of at least 500 and statins would
                                                          21
                                                               they excluded or washed out patients that were
                                                               receiving other triglyceride-lowering medications.
22
    not be thought of as a triglyceride-lowering
                                                          22
23
    therapy as you would think of niacin and fibrates
                                                          23
                                                                           So there is a distinction between a
    and so forth.
24
                                                          24
                                                               triglyceride-lowering medication and another agent
```

25

such as --

So let me get -- understand this. So

25

Q

1	Page 22 Q A lipid-altering therapy; right?	6 1	Page 228 A Well, again, I want to be careful		
2	Triglyceride	2	because obviously in the MARINE study statins were		
3	A No, the L the primary	3	permitted to be used.		
4	LDL-lowering	4	Q I'm not asking in the MARINE I'm		
5	Q All right.	5	asking about the claim.		
6	A therapy.	6	A 500 to 1500, the focus is on		
7	Q But an LD so would you would you		triglyceride-lowering medications.		
8	agree with me, if I'm looking at a venn diagram,	8	Q And patients on five who have over		
9	lipid-altering therapy could be drugs that treat	9	500 milligrams per deciliter of triglycerides, are		
10	any lipid and triglyceride-lowering therapies	10	also sometimes on statins; right?		
11	would be just within that a circle within that	11	A Yes.		
12	that treat that lower triglycerides; right?	12	Q Okay. So there are patients who		
13	A You're looking at VHTG, so it's a	13			
14	special group of patients.	14	have who are on this above the five between the 500 and the 15 who are also on a		
15	O And				
	~	15	statin. And my question is when we give them the		
16	A Very high triglycerides.	16	icosapent, does that mean that they are receiving		
17	Q 25 percent of them in the patent met		concurrent lipid-altering therapy?		
18	for example, I think you said were also on	18	MR. KENNEDY: Objection to form.		
19	statins	19	THE WITNESS: If they are receiving a		
20	A Yes.	20	combination of eico eicosapentaenoic and		
21	Q and/or ezetimibe.	21	another cholesterol or lipid-lowering medication.		
22	A I'm not	22	BY MR. CLEMENT:		
23	Q Right?	23	Q And, so, then they can't be considered		
24	A I'm not saying that I'm not	24	someone who is not receiving a concurrent		
25	discounting statins.	25	lipid-altering therapy; correct?		
	Dago 22	,	Daga 220		
1	Page 22' Q Okay.	7 1	Page 229 A Again, with with respect to the		
1 2		- 1	5		
	Q Okay.	1	A Again, with with respect to the		
2	Q Okay. A I'm just saying my my reading is	1 2	A Again, with with respect to the clinical trial, patients in the clinical trial		
2 3	Q Okay. A I'm just saying my my reading is in terms of the MARINE study was to exclude	1 2 3	A Again, with with respect to the clinical trial, patients in the clinical trial with triglyceride levels between 5- to 1500 could not be taking or had to be washed out of a		
2 3 4 5	Q Okay. A I'm just saying my my reading is in terms of the MARINE study was to exclude patients that were not on triglyceride-lowering medications because of the population being	1 2 3 4	A Again, with with respect to the clinical trial, patients in the clinical trial with triglyceride levels between 5- to 1500 could not be taking or had to be washed out of a triglyceride-lowering medication. They did not		
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	- /	- /	016 Z30 t0 Z33
1	Page 230 would be the case.		Page 232 it.
2	Q Okay. You also talked about Katayama;	2	Q But patient compliance is an age old
3	right?	3	problem, right, between doctor and patients?
4	A Correct.	4	A Well, it's not so much between doctors
5	Q In your declaration.	5	and patients. It's usually we try to do our
6	Let's turn to Katayama which, I guess,	6	job.
7	is in the '728 file wrapper.	7	Q Right.
8	Did I mark that one? I don't know if I	8	And the patients
9	marked that one yet.	9	A You can bring
10	MR. KENNEDY: I don't think so.	10	Q don't always do theirs?
11	MR. CLEMENT: Let's skip that for now.	11	A You can bring the horse to water.
12	I'll find it at the break.	12	Q Right. Okay.
13	BY MR. CLEMENT:	13	But patient compliance is an issue when
14	Q All right. Can a patient administer a	14	you're trying to treat a patient; right?
15	medication to his or herself?	15	A It can be.
16	A Yes.	16	Q It can be. Okay.
17	Q And that's by taking the medication?	17	So patients while you would like
18	A Yes.	18	them to always take the drug, they don't always?
19	Q So, I quess, one of the questions I'm	19	A Yes.
20	having and I'm not even sure this is a dispute	20	Q And they don't always take it as
21	between plaintiff and defendants on the term	21	prescribed maybe?
22	"administering". My view of it is that	22	A Correct.
23	administering can include the doctor prescribing.	23	Q But you do agree that administering
24	It can include all those steps before, but that it	24	could include the patient actually taking the
25	has to include the patient actually ingesting the	25	medication?
23	hab to include the patient actually ingesting the	25	medicación.
	Page 23:		Page 233
1	medication.	1	A Yes.
2	Is that your understanding?	2	Q So they can self-administer?
3	A No.	3	A Yes.
4	Q No, okay.	4	Q Which has nothing to do with writing a
5	Tell me where I'm wrong.	5	prescription; right? They're just taking the pill
6	A I write a prescription for a patient.	6	then?
7	I advise the patient to take the medication at X	7	A That's part
8	time. Patient goes on his or her way. I don't	8	MR. KENNEDY: Objection to form.
9	I don't know what happened. But as far as I'm	9	THE WITNESS: That's part of the
10	concerned, I administered the medication.	10	process. They they can't take the pill if I
11	Q So just by writing that script and	11	haven't prescribed it.
12	talking to the patient, that's administering?	12	BY MR. CLEMENT:
	7 Martin that is administration Time	13	Q Well, what if they just go an
13	A That is that is administering. I'm		
14	not going to be there to see to watch every	14	off-the-shelf medication, can they administer an
	not going to be there to see to watch every time the patient takes the medication. I I	14 15	off-the-shelf medication, can they administer an off-the-shelf medication to themselves, omega-3,
14 15 16	not going to be there to see to watch every time the patient takes the medication. I I presume that to be the case, but administering	15 16	off-the-shelf medication, can they administer an off-the-shelf medication to themselves, omega-3, whatever, fatty acids that are off the shelf?
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to 237 Page 234 Page 236 1 administration; right? Α Yes. 2 Yeah, I believe it was. Q What does "clear and convincing 3 And that's at column 12, line 49? evidence" mean to you? 4 Α I -- I would say clear and convincing 5 And they're defining oral 5 evidence is -- is -- it's the usual term. administration, right, in that -- in that 0 What does that mean, "usual term"? 7 paragraph? What does it mean to you? 8 Α 8 That it doesn't exist. That there's They are. 9 Is there anything about a prescription 9 evidence to -- to -- to otherwise refute. 10 being written in that paragraph? 10 So it's your understanding there's no 11 MR. KENNEDY: Objection to form. other -- in order to meet the clear and convincing THE WITNESS: I believe that evidence standard, there has to be no evidence 12 information is presented elsewhere in the otherwise to refute? 13 13 14 intrinsic evidence. To refute it, to refute what is viewed BY MR. CLEMENT: as -- as -- as it's been written. 15 15 16 0 Okay. But it's not in that paragraph; 16 Okay. What is your understanding of 17 right? 17 what "indefiniteness" means in the context of your 18 Not in this specific paragraph. declaration? 19 But what is in that paragraph is the 19 And feel free to glance through. 0 20 patient actually putting it in their mouth; right? 20 Yeah, I mean, as I say in paragraph 79, 21 In this particular paragraph, that's 21 Fails to inform a person of ordinary skill in the 22 the case. But elsewhere, there are other examples 22 art about the scope of invention with reasonable 23 within the intrinsic evidence demonstrating that 23 certainty. administration includes the action by a physician. 24 24 Q In general are statistically 25 But here they're defining oral significant changes always clinical meaning --Page 235 Page 237 administration; right? clinically meaningful? 1 2 Within this one paragraph. Α No. 3 Okav. Would you agree that it's your opinion 4 MR. CLEMENT: Why don't we -- have we that a -- and I'm looking at paragraph 81 -- that been going an hour. a substantial increase in lipid levels is one that 5 6 MR. KENNEDY: Yeah. Yeah. would affect how a clinician would respond to such 7 MR. CLEMENT: Let's take a break. an increase? 8 THE VIDEOGRAPHER: The time is Α We are going off the record. This And is that different for different 9 2:16 p.m. 9 Q concludes tape number 4. patients? 10 Could be. 11 (Recess -- 2:16 p.m.) 11 So for a different increase in lipid 12 (After recess -- 2:36 p.m.) 12 Q 13 THE VIDEOGRAPHER: The time is 13 levels depending on how else the patient presents, 14 2:36 p.m. This begins tape number 5. Going on you might treat them differently? 14 15 the record. 15 Α Depends on the -- the lipid you're Please proceed, Counsel. looking at and evaluating. 16 16 17 BY MR. CLEMENT: 17 0 What about for -- if you're looking at 18 Okay. Dr. Miller, if you turn to 18 triglycerides? 19 paragraph 79 in your report, and there you're 19 Α Yeah. You know, as we've said, the 20 talking about the definiteness; right? patients that have very high triglycerides are 2.0 21 Α Yes. 21 viewed differently than patients who have very 22 And you say that defendants -- you said 22 normal triglycerides. 23 you understand that defendants must prove by clear 23 Do you view all your patients who have and convincing evidence that a claim is 24 24 very high triglyceride levels, above the 500 mgs 25 indefinite; right? per dl, similarly or do you treat them as they --

Page 238 Page 240 individually as they come and might treat them 1 MR. KENNEDY: Objection to form. 2 differently depending how they present? 2 THE WITNESS: Right. So remember in a 3 I was -patient for whom triglyceride levels are in a very 4 MR. KENNEDY: Objection to form. high range, above 500, our -- our first and 5 THE WITNESS: I -- I treat patients foremost goal is to try to lower triglycerides. based on -- I treat them individually. Once we get it below 500, give or take, 7 BY MR. CLEMENT: then we move from the concern of pancreatitis risk 8 Based on their overall health and all to the concern of coronary risk. 9 their levels of different --9 BY MR. CLEMENT: 10 Α Yes. 10 And when you were talking about that -- markers; yeah? 5 percent -- when we were talking about the 11 Can you say without seeing a patient 5 percent number just a few minutes ago, was that 12 whether a 5 percent rise in LDL-C is clinically 13 13 based on your rule of six? 14 meaningful? Yeah, 5 to 6 percent is in part based on the rule of six. 15 MR. KENNEDY: Objection to form; 15 16 incomplete hypothetical. 16 0 In the rule of six, did you mention 17 THE WITNESS: Right. So as a -- and 17 that in the -- your opening declaration? 18 this is -- your question is outside the scope of 18 I believe I may have mentioned it in my 19 the patent; is that correct? response, my second --19 20 BY MR. CLEMENT: 2.0 Q Right. I'm asking about your opening. 21 Yeah. 21 Α I'm not sure if it was mentioned in the 22 Α Yeah, so if a patient -- you know, as a 22 opening, but I believe it was mentioned in the 23 clinician, that -- that is viewed as a threshold, 23 second. that a 5 percent change -- and in this particular 24 24 Ω Okay. I agree with you it was 25 case we're talking about approximate 5 percent mentioned in the second, but, again, you didn't Page 239 Page 241 increase in LDL. Was that what you were referring mention it in the first; right? 2 to? I -- I would have to go through that 3 0 A 5 percent rise, yes -again. I know it was mentioned in the second. 4 Α A 5 --So in paragraph 81 of your opening 5 -- increase. report -- declaration, you talk about a 6 -- percent rise in incr- -- in LDL substantial increase in lipid levels being one 7 would be viewed as kind of the threshold where -that would alter how a physician would view the 8 where I or another POSA might consider making dose patient's risk of developing a disease and would necessitate consideration of a new treatment or 9 adjustments. What if -- so 10 percent or 15 percent, change to existing treatment; right? 10 that would -- you would also consider that 11 11 clinical --12 12 Q So as a physician, would you consider 13 Α Yeah, I think about 5 percent give or 13 an increase of LDL-C from 90 to 100 significant? take the threshold above which we would make 14 14 Well, I think -- again, this is 15 changes, or we'd certainly consider making 15 hypothetical, and I think you would need to look changes. at the patient's overall risk and what other risk 16 16 17 But you would want to know more about 17 factors may be evident. 18 the patient before you decided whether or not to 18 0 How about a 100 to 106 rise in LDL? 19 make changes; right? 19 Α So, again, as I just mentioned before, We'd always want to know more about the 20 Α 20 this is hypothetical, and a 100 to 106 is an patient. 21 approximate 6 percent increase in LDL if my math 21 22 0 Is a 5 percent rise in an LDL-C 22 serves me correctly. Again, that is the -- that 23 level -- is that -- for patients with over 500 mgs 23 is a little bit -- right around the threshold 24 per dl, is a 5 percent rise in an LDL-C level a 24 where you need to at least consider that. 25 treatment challenge? 25 But you'd want to see the patient;

	Page 242		Page 244		
1	right?	1	that that that citation to that?		
2	A I don't play telemedicine.	2	MR. KENNEDY: Objection to form.		
3	Q Okay. So let's look at paragraph 83 of	3	THE WITNESS: I was referring more to		
4	your declaration, and you're saying, Doctor you	4			
5	say, The applicants submitted a declaration from	5	3.7		
	Dr. Bays reporting a 4-gram per day dose of AMR101 reduced triglycerides over 35 percent without a	6			
7			Q Right. But this is a paragraph you put		
8	significant change in LDL-C. Do you see that?	8	in your declaration in this section, and I I		
10	A Yes.	10	thought it was what was the purpose of putting it in there if it wasn't to support what a		
11	Q So what was that significant change; do	11	substantial change is? It's under		
12		12	the substantially "without substantially		
13	you know or without a significant change?	13	-		
14	And I think you have the '727 file wrapper there with you if you need to look at that	14	increasing" claim term; right? MR. KENNEDY: Objection to form.		
15	and	15	THE WITNESS: Let me see if that's		
16	A Yeah, why don't I don't I take a	16	actually I'm I'm looking at a on a		
17	look at that.	17	different page. Let me see if I can find that		
18	(Witness reviews document.)	18	specific page.		
19	So for LDL cholesterol, the difference	19	(Reviews document.)		
20	between the Amarin 4 grams a day versus placebo	20	So now I'm looking at on page 20 which		
21	was approximately 2 percent	21	is actually 0317 Bates number 9808 where he		
22	Q Okay. Which	22	mentions this with respect to reduction in ApoB		
23	A and 3 percent.	23	and substantially no increase in LDL as well as		
24	Q Which page are you looking at?	24	the satisfaction of a long felt, unmet medical		
25	A I'm looking at page 8246.	25	need.		
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	Page 243		Page 245		
	rage 245		rage 245		
1	Q 8246.	1	BY MR. CLEMENT:		
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2	Q 8246. And what numbers are you looking at? A I'm looking at Amarin 4 grams a day versus placebo, and this is baseline percent	2 3 4	BY MR. CLEMENT: Q Okay. Where is that again? You're on page 9-9808? A I'm on page 9808.		
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	And what numbers are you looking at? A I'm looking at Amarin 4 grams a day versus placebo, and this is baseline percent change from baseline in the MARINE study. Q And that was a 2.3 A Correct. Q Negative 2.3; right? A Negative 2.3. Q So that's not five or six; right? A That is not five or six. Q And you also look at the Weintraub or, no, I'm sorry. In the '727 file wrapper, you also and Dr. Bays was talking about significant change and not substantial; is that correct? MR. KENNEDY: Objection to form. THE WITNESS: Let me see the specific wording that he used. I'd have to look to see exactly. Let's see. (Reviews document.) Right. He says significant change. BY MR. CLEMENT:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. CLEMENT: Q Okay. Where is that again? You're on page 9-9808? A I'm on page 9808. Q Where are you reading from? A I'm reading from the second paragraph. Q The one that begins which one? Beginning, Even if a prima facie case or A Yes. Q Okay. Is this a the Bays declaration? A Well, this is in the prosecution history, and it may be let's see. It may be from one of the examiners, but it does refer to Bays. Q Where does it refer to Bays? A Well, if you go to the previous page, it talks about Bays Declaration III. Q Okay. But, again, my question is was there something you cited to I was looking at your declaration, paragraph 80 no, wait I'm sorry paragraph 83. And I'm just trying to get an understanding of why you cited to		

Page 246 Page 248 argument that substantial change means 5, 1 doesn't talk about 5 to 6 percent; right? 6 percent? 2 He does not talk about 5 --2 Α 3 Yeah, I mean Bays says with -- with an Q Okay. LDL rise may necessitate the initiation of -- to 6 percent. Α 5 lipid-altering drug therapy. Q But you say -- but you say Weintraub 6 But where does he say what that -- what does; right? 7 rise? Is it any rise? Is it 5 to -- where does 7 Α That was -- that was my recollection. it say 5 or 6 percent? 8 Do you want to show me where? 8 0 9 (Witness reviews document.) 9 Α (Witness reviews document.) 10 Yeah, the 5 to 6 percent is -- is 10 Yeah, it's like he says -- and I say mentioned in other parts of the prosecution this on -- on number 85, Dr. Weintraub explained 11 history. I'll find those for you. in a declaration submitted to the patent office: 12 Even a small increase in LDL caused by 13 No, that's fine. I'm just wondering --13 14 is it mentioned in the -- in the -- and we can go triglyceride-lowering drug can have serious complications for patient. For example, an 15 16 I just want to know, for the record, is 16 increase in concentration of LDL by about 17 there anything in the Bays declaration that you 17 6 percent can result in a need to double the 18 cite to in page 83 of your report that supports concentration of a statin. 19 your 5 to 6 percent number for substantial change? 19 To mitigate this increase in LDL. This 20 I think there is, but I would actually 20 can result in an increase in cost for the therapy 21 have to go through the entire document. 21 and a significantly higher risk of statin-related 22 Sitting here today -- sitting here 22 adverse events. 23 today, you can't do that? I mean, you cited --23 And then subsequent to that in 86 --24 I can do that. mentioned that typically an increase in LDL of Α 24 25 25 about 5 to 6 percent in a hyperlipidemic patient 0 Okay. You --Page 249 Page 247 1 Α T can -would cause a physician to consider additional Q -- cited --LDL-lowering treatment. The ATP guidelines 3 -- do that sitting here today, but it's explain that to decrease LDL by 6 percent double going to take sometime. the dose of his statin. 5 All right. Why don't you take, you 5 Let's go one at a time. Okay? 6 know, five or ten minutes and see if you can do Α 7 So you're relying on this paragraph at 8 Α Okay. the top of page 38 for your basis saying that 9 Weintraub supports your 6 percent is a substantial (Witness reviews document.) 9 I know Dr. Weintraub says it. increase; correct? 10 10 Α It's substantial enough to consider a 11 Q Okay. 11 medication. 12 So I will find where Dr. Bays says it. 12 13 (Witness continues reviewing document.) 13 0 Okay. Is the word "substantial" in 14 May -- I see you flipping through 14 that paragraph? 15 there. Are you looking at the Bays declaration --15 Α No, he uses --Α I'm looking --He uses small increase; right? He 16 16 0 17 Q -- or the --17 doesn't even say substantial. He says, Small 18 Α I'm looking at the Bays declaration 18 increase; right? 19 right here, specifically right here. 19 Α Right. Because what he's -- what he's 20 (Witness continues reviewing document.) 20 basing it on is the relative differences between 21 Yes, he -- he talks primarily about the 21 what was observed in -- in the clinical trials increases in LDL-C with other therapies, and inasmuch as -- in some cases the increase is a lot 22 22 23 not -- he doesn't specifically talk about 5 to 23 higher. 24 6 percent, but -- but Weintraub does. 24 He says -- he's saying, Even a small 0 25 Okay. So let's stick with Bays. Bays increase

	02/13	, 2 .	250 to 253
	Page 250		Page 252
1	A Yeah.	1	Amarin AMR101; correct?
2	Q He never says substantial. He says,	2	A That is correct.
3	Small?	3	Q And it says, Lovaza data in borderline
4	A Yeah. Correct.	4	high/high triglycerides.
5	Q So he doesn't say 6 percent is	5	So does that even rate relate to
6	substantial. He says that might be a small	6	very high triglycerides?
7	increase; right?	7	A No, but that may be where the small
8	A Right. I believe I said substantial.	8	increase comes from because when you look at the
9	Q You said substantial. Exactly.	9	4.5 percent compared to results with Lovaza 4
10	Let's look at what else you cite. You	10	grams a day in patients with very high
11	go on and in that same paragraph 85 you have	11	triglycerides, you there was a 44.5 percent
12	another citation to the request for continued	12	increase in LDL. So it's the 4.5 percent is
13	examination; right?	13	is smaller compared to the 44.5
14	A Yes.	14	Q Understood.
15	Q Okay. And that's at AMRN3059047, but	15	A percent.
16	first can you turn to AMRN3059035.	16	Q But your is the 4 are you I
17	Do you see that's I'm sorry. Let me	17	guess, let me ask this question. Are you relying
18	know when you get there. That's a request for	18	on this 4.5 percent number for your the basis
19	continued examination.	19	for your understanding that without substantial
20	Do you see that?	20	increase in LDL-C is a substantial you know,
21	A Request for continued examination, yes.	21	that it would be understood to be 6 percent by a
22	Q Do you know what that is?	22	person of ordinary skill in the art?
23	A It sounds like what is stated.	23	MR. KENNEDY: Objection to form.
24	Q Okay. Do you have any other knowledge	24	THE WITNESS: Yeah, you know, I'm
25	as to what one of those what a request for	25	putting I'm trying to put this into context.
	Page 251		Page 253
1	continued exam is that something the examiner	1	And and as you see in paragraph 85, I
2	says?	2	specifically say that this was reported in
3	A I'm I'm not a patent attorney, so	3	patients the 4.5 percent LDL increase was
4	I'm just taking it for what it says.	4	reported in patients in the borderline high-TG to
5	Q Okay. And your page your citation	5	high-TG patient population.
6	to page 9047 is within this request for continued	6	BY MR. CLEMENT:
7	examination document that you're not 100 percent	7	Q Okay.
8	sure of what it is; right?	8	A So that is that's the context by
9	A Well, I'm I'm I'm presuming it's	9	by which I put that.
10	related to the unexpected results of Amarin 101.	10	Q Okay. So is that supporting your 5 to
11	Q Well, there's a section on that; right,	11	6 percent number for substantial increase, or is
12	on page 047 of that document? The whole document	12	it just nice information to know?
13	is not related to the unexpected results; right?	13	A I think it's all additional
14	A Right, but	14	information. I think where the information is
15	(Witness reviews document.)	15	based upon a number of different areas that
16	So I am presuming that this is related	16	include the intrinsic evidence, so it's
17	to claims that for the patent.	17	prosecution history, specification.
18	Q Okay. Now, what do you you rely on	18	And, so, this is all part of the
19	this I guess, this 4.5 number on the table the	19	prosecution history.
20	9047; is that what you're	20	Q Understood.
21	A Correct.	21	But does that support your
22	Q And there's a footnote with regard to	22	determine this 4.5 percent number, are you
23	that; right?	23	using that to say that that's the 5 to
24	A There is a footnote.	24	6 percent as a person of ordinary skill in the
25	Q And that's for Lovaza data not for	25	art would understand that a 5 to 6 percent change

	02/15	•	016 254 tO 257
	Page 254		Page 256
1	in patients with very high triglycerides would	1	statis statistical significant; right?
2	know that's what substantial change means?	2	A I see that.
3	MR. KENNEDY: Objection to form.	3	Q And you're not relying on that entry
4	THE WITNESS: I think that 4.5 percent	4	for support of what "substantial change" means;
5	increase despite the fact that it's in a	5	correct?
6	borderline high TG to TG patient population, a	6	A Correct.
7	person of ordinary skill in the art would would	7	Q And you know in footnote 2 they talk
8	see that, would notice that.	8	about this Lovaza approval package.
9	BY MR. CLEMENT:	9	Do you see that?
10	Q Would notice that.	10	A I see that sentence.
11	Would they would they assume that	11	Q Have you ever seen the Lovaza approval
12	supports your 5 or 6 percent number for what a	12	package?
13	substantial change is in the very high	13	A I believe I have.
14	triglyceride?	14	Q Did you look at it in context for
15	A Well, obviously this was not done in a	15	preparing your declarations in these case in
16	very high triglyceride, and I pointed that out.	16	this case?
17	It's in paragraph 85. I specifically say it's	17	A If it's within this prosecution
18	borderline high to high TG.	18	history, then I did.
19	Q Okay. And it doesn't say anywhere in	19	Q No, I don't think it is.
20	here that there's substantial, but that means	20	A Then I may not have.
21	substantial; right? I'm looking on what's on this	21	Q You also rely on a Baigent article; is
22	page 9047.	22	that right?
23	A Yeah, I'm not sure if if that	23	A Baigent.
24	specific term was used. It doesn't detract from	24	Q Baigent.
25	the fact that I think that substantial is	25	A Yes.
1	Page 255 clinically meaningful.	1	Page 257 Q I'll get a copy of that for you.
2	Q And do you see that in the footnote 2	2	MR. CLEMENT: Let's mark as Miller
3	on that page?	3	Exhibit 20 a copy of a the Baigent article
4	A Which page?	4	Bates numbers 3130228 through 0239.
5	Q The same page we were looking at, 9047.	5	(Miller Deposition Exhibit 20 was
6	Do you see the footnotes at the bottom	6	(HILLET Deposition Emiliate It mas
7	referring to the table?	7	marked for identification and attached to the
			marked for identification and attached to the
1 8	A The statistical reviews noted that the		transcript.)
8	A The statistical reviews noted that the	8	transcript.) BY MR. CLEMENT:
9	significance of the small increase requires	8 9	<pre>transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller</pre>
9	significance of the small increase requires clinical judgment.	8 9 10	<pre>transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right?</pre>
9 10 11	significance of the small increase requires clinical judgment. Q All right. This says a small increase	8 9 10 11	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes.
9 10 11 12	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase;	8 9 10 11 12	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen
9 10 11 12 13	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right?	8 9 10 11 12 13	<pre>transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right?</pre>
9 10 11 12 13 14	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right? A Right because it is a small increase	8 9 10 11 12 13 14	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right? A Yes.
9 10 11 12 13 14 15	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right? A Right because it is a small increase relative to the 44.5 percent	8 9 10 11 12 13 14 15	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right? A Yes. Q And that's something you had attached
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9 10 11 12 13 14 15 16 17 18 19 20 21	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right? A Right because it is a small increase relative to the 44.5 percent Q Okay. A noted below that. Q But they said it's was a small increase, not a substantial increase; correct? A Correct. Q Okay. What about the 8.4 percent number on the Epadel, right? Do you see that?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right? A Yes. Q And that's something you had attached as an exhibit to your declaration? A Correct. Q It wasn't within the file history of any patent; right? A I would have to check that. Q Would you consider this to be actually, I guess, would you consider this to be
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right? A Right because it is a small increase relative to the 44.5 percent Q Okay. A noted below that. Q But they said it's was a small increase, not a substantial increase; correct? A Correct. Q Okay. What about the 8.4 percent number on the Epadel, right? Do you see that? A Correct.	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right? A Yes. Q And that's something you had attached as an exhibit to your declaration? A Correct. Q It wasn't within the file history of any patent; right? A I would have to check that. Q Would you consider this to be actually, I guess, would you consider this to be extrinsic evidence?
9 10 11 12 13 14 15 16 17 18 19 20 21	significance of the small increase requires clinical judgment. Q All right. This says a small increase there or not? Sub substantial increase; right? A Right because it is a small increase relative to the 44.5 percent Q Okay. A noted below that. Q But they said it's was a small increase, not a substantial increase; correct? A Correct. Q Okay. What about the 8.4 percent number on the Epadel, right? Do you see that?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	transcript.) BY MR. CLEMENT: Q Dr. Miller, we put before you as Miller Exhibit 20 a copy of the Baigent article; right? A I have that, yes. Q And that's something you've seen before; right? A Yes. Q And that's something you had attached as an exhibit to your declaration? A Correct. Q It wasn't within the file history of any patent; right? A I would have to check that. Q Would you consider this to be actually, I guess, would you consider this to be

1	Page 258 Q Did you find this article or was this	1	Page 260 don't you recall putting this paper in here for
2	something counsel provided to you?	2	that support of that statement but not in
3	A I've known about this article for	3	support of your opinion that substantial increase
4	years.	4	means 5 or 6 percent; right?
5	Q Again, did you find this article or was	5	A Again, it's really the totality of data
6	this something that counsel provided to you for	6	that I'm looking at. I'm looking at I'm
7	purposes	7	considering all of the all of the evidence
8	A I	8	whether it's based on the specification or based
9	Q of drafting your declaration?	9	on the prosecution history or even here some of
10	A I actually think I may have brought	10	the extrinsic evidence that this this statement
11	this article up	11	is based on the totality of evidence that I have.
12	Q Okay.	12	Q Okay. But, again, do you recall,
13	A to their attention.	13	sitting here today, any statement in this and I
14	Q And it says a 2005 article?	14	understand you're looking at the totality of the
15	A I believe that's the date.	15	evidence. I just want to know for purposes of my
16	O And where in this article does it	16	small mind is there anything in here that says
17	define or talk about what a substantial increase	17	substantial increase should be 5 or 6 percent?
18	is for LDL-C?	18	A And and as I pointed out before,
19	MR. KENNEDY: Objection to form.	19	the the sentence specifically talks about the
20	THE WITNESS: Yeah, I'm not sure that	20	increase in LDL. There was a corresponding
21	that is defined in this article. The point of	21	increase in cardiovascular risk.
22	bringing this article was to show that as LDL	22	So if you have a 5 or a 10 percent
23	increases, the risk for cardiovascular events also	23	increase in LDL, then you're going to have an
24	increases.	24	increase in cardiovascular risk.
25	BY MR. CLEMENT:	25	Q It says for every increase. So if you
			2
1	Page 259 Q Okay. But it doesn't say anything	1	Page 261 have a 1 percent, you have an increase; right?
1 2	9	1 2	5
	Q Okay. But it doesn't say anything		have a 1 percent, you have an increase; right?
2	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct?	2	have a 1 percent, you have an increase; right? A Correct.
2	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the	2	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not
2 3 4	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the	2 3 4	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not mentioned anywhere in the patent; right?
2 3 4 5	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the the the way this is read is a POSA would	2 3 4 5	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not mentioned anywhere in the patent; right? A I'd have to go through all those
2 3 4 5 6	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the the the way this is read is a POSA would understand that for every increase in LDL there	2 3 4 5	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not mentioned anywhere in the patent; right? A I'd have to go through all those patents, but I'm not sure.
2 3 4 5 6 7	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the the the way this is read is a POSA would understand that for every increase in LDL there was a corresponding increase in cardiovascular	2 3 4 5 6	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not mentioned anywhere in the patent; right? A I'd have to go through all those patents, but I'm not sure. Q And then finally you rely on the ATP
2 3 4 5 6 7 8	Q Okay. But it doesn't say anything about your 5 or 6 percent number; correct? A I'm not sure that it was put in the context of the 5 to 6 percent. In fact, the the the the way this is read is a POSA would understand that for every increase in LDL there was a corresponding increase in cardiovascular risk, and that's shown in the paper in Figure 3.	2 3 4 5 6 7 8	have a 1 percent, you have an increase; right? A Correct. Q And the Baigent article, that's not mentioned anywhere in the patent; right? A I'd have to go through all those patents, but I'm not sure. Q And then finally you rely on the ATP guidelines, right, for your explain that to
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	<u> </u>		
	Page 262		Page 264
1	Q I'm asking does that refer to a	1	D.
2	lowering.	2	Q All right. But no mention of
3	A That is correct.	3	substantial increase; right?
4	Q And the patent refers to an increase;	4	A No. It talks about 5 percent
5	right?	5	increase less than 5 percent.
6	A Yes.	6	Q Talks about ten, 50, 20, 30, 35 it
7	Q I don't see the word "increase" in here	7	talks about all of them; right?
8	at all, do you?	8	A Right. But, again, as I as I
9	A No, but as I said it is it is	9	pointed out 5 to 6 percent would be the threshold
10	converse is also holds.	10	by which we would consider adjustment of therapy
11	Q That's what you say, but I didn't see	11	and and, yes, so 10 percent for sure,
12	it in that article. Did you?	12	20 percent and 30 percent and higher levels of
13	A No, but you would see it in the Baigent	13	course, but 5 percent is that lower threshold
14	article where you see that association quite well.	14	limit.
15	And that gets back to the point if you	15	Q Right.
16	look at Figure 3 of this relationship between LDL	16	But it doesn't say that's a substantial
17	and coronary disease.	17	increase; right? It just mentions 5 percent;
18	Q One second. I've got to find my page.	18	correct?
19	I'm sorry. Okay. Go ahead. Sorry.	19	A Correct. And, again, looking at the
20	A And and, so, what what has been	20	totality of evidence in the prosecution history as
21	established what we had known for many years is	21	part of the intrinsic evidence, so all of these
22	that as you go up in this association, as for	22	are pieces that when put together provides, I
23	every LDL increase, there is an increased risk of	23	think
24	events. Conversely as you reduce LDL you also	24	Q Did you cite to column 5, lines 37 to
25	have a similar reduction in coronary events.	25	46 in any of your declarations of the '728 patent
	Page 263		Dago 26E
I 1		1	Page 265
1 2	So both directions work.	1 2	in support of your understanding of the term
2	So both directions work. Q But Baigent doesn't mention anything	2	in support of your understanding of the term "substantial increase"?
2 3	So both directions work. Q But Baigent doesn't mention anything about the 5 or 6 percent or rule of six at all;	2 3	in support of your understanding of the term "substantial increase"? A I don't know if I if I did, but now
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Page 266
                                                                                                              Page 268
                 I don't know if it's in the patent.
                                                              1
                                                                              MR. CLEMENT: Sounds great.
                                                                                                             Thank you.
 2
                 Wouldn't doubling the dose of a statin
                                                                              THE VIDEOGRAPHER: The time is
 3
     be some sort of a lipid -- additional
                                                                  3:44 p.m. This concludes today's deposition given
                                                                  by Dr. Michael Miller. We are now off the record.
     lipid-lowering therapy?
 5
                 MR. KENNEDY: Objection to form.
                 THE WITNESS: Again, the focus here was
 7
     to evaluate and treat patients with very high
     triglycerides. And the focus is lowering
                                                                              (Signature having not been waived, the
8
9
     triglycerides. The focus wasn't to specifically
                                                                  Videotaped Deposition of MICHAEL MILLER, M.D.,
10
     also lower LDL. It was to lower triglycerides.
                                                                  ended at 3:44 p.m.)
                 By the way, this medication seemed to
                                                             11
11
     not raise LDL compared to other medications that
                                                             12
12
     lowered very high triglyceride and did raise LDL.
13
                                                             13
14
     This did not do that.
          BY MR. CLEMENT:
                                                             15
15
16
                 Understood.
                                                             16
17
                 But is there anything in the patent
                                                             17
18
     that talks about -- that you should double the
                                                             18
19
     dose of statins to figure out what substantial
                                                             19
20
     decrease in LDL means?
                                                             20
21
                 I'm not sure.
                                                             21
22
                 Even doubling the dose of a statin,
                                                             22
23
     that would be additional lipid-altering therapy;
                                                             23
24
     correct?
                                                             24
25
                                                             25
          Α
                 Yes. Again, I'm not sure that's
                                                 Page 267
                                                                                                              Page 269
                                                                 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
     relayed in the patent.
                                                                          I, Dana C. Ryan, Registered Professional
 2
                 MR. CLEMENT: Okay. Why don't we take
                                                                 Reporter, Certified Realtime Reporter, the officer
 3
     a break.
                                                                 before whom the foregoing proceedings were taken
                 MR. KENNEDY: Okay.
                                                                 do hereby certify that the foregoing transcript is
                 THE VIDEOGRAPHER: The time is
 5
                                                                 a true and correct record to the best of my
 6
     3:28 p.m. We're going off the record.
                                                                 ability of the proceedings; that said proceedings
 7
                 (Recess -- 3:28 p.m.)
                                                                 were taken by me stenographically and thereafter
 8
                 (After recess -- 3:43 p.m.)
                                                                 reduced to typewriting under my supervision; and
                 THE VIDEOGRAPHER: The time is
9
                                                                 that I am neither counsel for, related to, nor
     3:43 p.m. We're back on the record.
10
                                                                 employed by any of the parties to this case and
11
                 Please proceed, Counsel.
                                                                 have no interest, financial or otherwise, in its
                 MR. CLEMENT: Okay. Dr. Miller, thank
12
                                                                 outcome.
                                                             13
13
     you very much for your time today. At this point
                                                             14
                                                                          IN WITNESS WHEREOF, I have hereunto set
14
     in time, we have no further questions.
                                                                 my hand and affixed my notarial seal this 28th day
15
                 MR. KENNEDY: Amarin has no questions
                                                                 of February 2018.
     for you at this time.
16
                                                                 My Commission expires:
17
                 I would like to designate the
                                                             18
                                                                 July 15, 2020
18
     transcript highest level of confidentiality
                                                             19
19
     because I think some internal documents were
                                                             20
     marked. We can talk at some point about, you
2.0
     know, limiting the designation, but I would like
21
                                                             22
     to make that designation.
22
23
                 I would like to reserve the witness'
                                                             23
                                                                 NOTARY PUBLIC IN AND FOR THE
                                                             24
                                                                 DISTRICT OF COLUMBIA
    right to read and sign the transcript, then I
24
                                                             25
25
    think we're done.
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1	Page 270	1	ACKNOWLEDGMENT OF DEPONENT	Page	272
2		2	I, Michael Miller, M.D., do hereby		
3	Please read your deposition over	3	acknowledge that I have read and examined the		
4	carefully and make any necessary corrections. You	4	foregoing testimony, and the same is a true,		
5	should state the reason in the appropriate space	5	correct and complete transcription of the		
6	on the errata sheet for any corrections that are	6	testimony given by me and any corrections appear		
7	made.	7	on the attached Errata sheet signed by me.		
8	After doing so, please sign the errata	8			
9	sheet and date it.	9			
10	You are signing same subject to the	10			
11	changes you have noted on the errata sheet which	11			
12	will be attached to your deposition.	12	(DATE) (SIGNATURE)		
13	It is imperative that you return the	13			
14	original errata sheet to the deposing attorney	14			
15	within thirty (30) days of receipt of the	15	CERTIFICATE OF NOTARY PUBLIC		
16	deposition transcript by you. If you fail to do	16	Sworn and subscribed to before me this		
17	so, the deposition transcript may be deemed to be	17	day of,		
18	accurate and may be used in court.	18			
19		19			
20		20			
21		21	NOTARY PUBLIC MY COMMISSION EXPIRES		
22		22	NOTARY PUBLIC MY COMMISSION EAPTRES		
23		23			
24		24			
25		25			
23		23			
	Page 271				
1	ERRATA SHEET				
2	IN RE: AMARIN PHARMA, INC., et al. v. WEST-WARD				
3	PHARMACEUTICALS CORP., et al.				
4	RETURN BY:				
5	PAGE LINE CORRECTION AND REASON				
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25	(DATE) (SIGNATURE)				

PAGE	LINE	CORRECTION AND REASON
41	18	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
53	17	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
54	5	"proceeded" to " preceded" / Transcription Error
56	7	"shown" to "known" / Transcription Error
58	13	"Heartland" to "Heart, Lung, and" / Transcription Error
99	10	"concur" to "refer" / Transcription Error
109	5	"simulation" to "scintillation" / Transcription Error
128	1	"microprotein" to "lipoprotein" / Transcription Error
131	8	"low" to "lowering" / Transcription Error
172	25	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
194	14	"Amarin at 2 grams a day and Amarin 101" to "AMR 101 at 2 grams a day and AMR 101" / Transcrip
194	18	"Amarin 101 is Amarin 101" to "AMR 101 is AMR 101" / Transcription Error
195	3-4	"Amarin 101" to "AMR 101" / Transcription Error
195	6	"Amarin 101" to "AMR 101" / Transcription Error
200	4	"who" to "two" / Transcription Error
200	20	"total unsaturated" to "total and saturated" / Transcription Error
222	25	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error
227	4	"were not" to "were" / Transcription Error
228	20	"eicosapentaenoic" to "eicosapentaenoate" / Transcription Error

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0070

1	ACKNOWLEDGMENT OF DEPONENT
2	I, Michael Miller, M.D., do hereby
3	acknowledge that I have read and examined the
4	foregoing testimony, and the same is a true,
5	correct and complete transcription of the
6	testimony given by me and any corrections appear
7	on the attached Errata sheet signed by me.
8	
9	
10	3/20/18 Sunt Culling
11	1/W/10
12	(DATE) (SIGNATURE)
13	
14	
15	CERTIFICATE OF NOTARY PUBLIC
16	Sworn and subscribed to before me this
17	day of,
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21	NOTARY PUBLIC MY COMMISSION EXPIRES
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